IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION **This Document Relates to: All Actions**	**Master Docket: Misc. No. 21-mc-1230-JFC** **MDL No. 3014** **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR MEDICAL MONITORING AND DEMAND FOR JURY TRIAL**

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Plaintiffs Drew Pendleton, Russell Autry, Deanna Melcher, Paul Bailey, Christine DiJohn, Patrick Nielson, Sylvia McDaniel, Jim Wolff, Jill Leavenworth, Jose Toscano, Jeffrey Boyle, Patricia Ragland, Tara Fields, Dennis Morris, Randy Paris, Brian McCarty, Michael Wheeler, Danny Baran, Debra Wilson, Michael Dusza, Steve Abarr, Sharon Cathers, Andrew Fisher, Doris Margoles, Wilbert Cotton, Quinton Goodall, Peter Bellotti, Prinna Boudreau, John Young, Danny David, Boniface Mills, Christopher Glaub, Elizabeth Lemus, Sabrina Malone, Aaron Taylor, Joe David Dennett, Beth Rodgers, Hugo Barragan, Sonia Diaz, Bruce Ginsberg, Deana King, Jeffrey Bartalo, Rachel Hock, Chad Wells, Arthur Hibbard, Joseph Hoffman, Marilyn Sweeney, Antonio Perez Bonano, Diane Lamontagne, Stephen Flannery, Susan Bakaitis, Jeffrey Kemp, Sarah Claunch, Paul Panzera, Martin Humphries, David Martin, Madaline Harbor, Elizabeth Heilman, Cameron Rose, Jose Lopez, Robert Peebles, Dennis Caling, Brent Hamlin, and Donald Rucker ("Plaintiffs" or "Medical Monitoring Class Plaintiffs"), individually and on behalf of all others similarly situated, through the undersigned counsel, allege as follows:

1. The Medical Monitoring Class Plaintiffs file this Consolidated Amended Class Action Complaint for Medical Monitoring and Demand for Jury Trial ("Medical Monitoring Class Complaint") against Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., Philips RS North America LLC, and Philips RS North America Holding Corporation (collectively, "Philips" or the "Philips Defendants"), bringing claims of, among other things, negligence, strict liability, medical monitoring, fraudulent and negligent misrepresentations and omissions, and breach of express and implied warranties.

2. Pretrial Order #14 ("PTO 14") (Doc. 573), set forth an orderly and efficient process for filing Consolidated Amended Class and Master Complaints. Pursuant to PTO 14, this Medical Monitoring Class Complaint is one of three master complaints being filed in this multi-district

litigation. The filing of three separate master complaints is only to streamline the issues within each of the pleadings for the mutual convenience of both the Court and the parties. Medical Monitoring Class Plaintiffs do not waive any claims that are not asserted here, or that are asserted in one of the other master complaints, including the Consolidated Second Amended Class Action Complaint for Economic Losses (Doc. 637) ("Economic Loss Complaint"), which was filed on behalf of: "All persons or entities in the United States who purchased, otherwise acquired, or leased a Recalled Device but did not resell it." *See* Economic Loss Compl., ¶ 260.

I. NATURE OF THE ACTION

3. Philips manufactures and sells certain lines of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are commonly used to treat sleep apnea; and mechanical ventilators ("ventilators"), which treat respiratory failure. The primary function of these devices is to blow air into patients' airways. CPAP and BiPAP machines are intended for use during sleep while ventilators are used continuously when needed.

4. On June 14, 2021, Philips announced a recall of millions of its CPAP and BiPAP machines and ventilators (the "Recall"). Each of these recalled products (individually referred to herein as a "Recalled Device," or collectively, as the "Recalled Devices") contain polyester-based polyurethane ("PE-PUR") foam for sound abatement. Despite knowing at least as far back as 2015 that PE-PUR foam degrades and should not be used in the Recalled Devices, Philips waited until June 2021 to issue the Recall and notify the public. In its Recall, Philips publicly announced that the PE-PUR foam may break down into particles and be inhaled or ingested, and may emit volatile organic compounds ("VOCs") that may be inhaled, resulting in "serious injury, which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude

5. permanent impairment"[1] (referred to herein as the "Defect"). Philips stated that the potential risks of exposure due to such chemicals include "headache/dizziness, irritation (eyes, nose respiratory tract, skin), hypersensitivity, nausea, vomiting, toxic and carcinogenic effects."[2] Philips' announcement to doctors advised that these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."[3]

6. On July 22, 2021, the U.S. Food and Drug Administration ("FDA") confirmed the severity of the issues described in the Recall and classified the Recall as Class I or "the most serious type of recall," meaning use of the Recalled Devices "may cause serious injuries or death."[4]

7. Philips knew about the serious risk caused by the Recalled Devices long before the Recall. At a minimum, Philips should have known about the risks caused by PE-PUR foam degradation when it was testing the foam pursuant to FDA regulations. And certainly, Philips knew as far back as 2008 that there were serious problems with the foam in the Recalled Devices because Philips received customer complaints about "contaminants, particles, foam, debris, airway, particulate, airpath, and black."[5]

8. Indeed, the FDA conducted an investigation in or around 2021, and thereafter issued a redacted report on November 9, 2021, detailing its findings that demonstrate Philips knew

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[1] Philips Recall Notices dated 6/14/2021 (attached hereto as Exhibit "A"). All attached Exhibits and reference material are incorporated as if fully stated herein.

[2] *Id*.

[3] Sleep and respiratory care update: Clinical information for physicians: philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Aug. 15, 2022).

[4] https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and (last accessed June 16, 2022).

[5] A redacted version of the FDA's 483 Report issued on November 9, 2021 is available here: https://www.fda.gov/media/154244/download (last accessed Aug. 12, 2022). ("483 Report").

that the PE-PUR foam degraded into hazardous substances.[6] The FDA discovered emails dating back to October 2015 from Phillips' raw foam supplier regarding degradation issues.[7] Additionally, the FDA found that, in November 2015, Phillips engaged in preventative maintenance on certain Recalled Devices in response to PE-PUR foam degradation issues and complaints, yet failed to conduct any "further investigation, health hazard evaluation, risk analysis, or design review" on any of the Recalled Devices that use the same PE-PUR foam.[8] To be sure, the FDA found that "there were at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Phillips] was aware of issues related to potential foam degradation and or Volatile Organic Compound (VOC) emissions."[9]

9. In addition, according to the FDA, beginning in 2015, Philips received data from a variety of sources regarding the degradation of the PE-PUR foam contained within the Recalled Devices including customer complaints, test reports, information from suppliers, and information from another entity owned by the ultimate parent company of Philips.

10. Despite knowing the risks associated with PE-PUR foam, Philips failed to disclose that the Recalled Devices were defective when manufactured and sold until many years later. In fact, it was only after Philips launched its next generation of CPAP/BiPAP machines – the DreamStation 2 devices – which do not contain PE-PUR foam, that Philips announced on April 26, 2021, that its previous generation DreamStation products and other CPAP, BiPAP, and ventilator devices posed serious health risks to users. Philips then waited an additional seven weeks before it initiated the Recall of the dangerously defective machines in the United States. Shortly

[6] *See generally id*.

[7] *Id*. at 18.

[8] *Id*. at 2.

[9] *Id*. at 3.

thereafter, Philips expanded its recall of defective CPAP, BiPAP, and ventilator devices worldwide.[10]

11. Philips' flagship product line and its top selling CPAP Recalled Devices are its DreamStation devices. On September 1, 2021, Philips received authorization from the FDA to begin a repair and/or replacement process for affected DreamStation devices in the United States.[11] However, the repair and replacement program was ineffective. DreamStation customers were not told when they might receive a replacement device nor were they given any specifics as to how the replacement program would work. In addition, the repair and/or replacement program was limited in that it only impacted DreamStation Recalled Devices and not any other Recalled Device.

12. The Recalled Devices are:

- E30
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C Series ASV, S/T, AVAPs
- OmniLab Advanced Plus
- SystemOne (Q Series)
- DreamStation CPAP, Auto CPAP, BiPAP
- DreamStation Go CPAP, APAP

[10] *See* https://www.philips.com.au/healthcare/e/sleep/communications/src-update. Other impacted countries include, but are not limited to Australia, Canada, Israel, and Chile.

[11] https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-and-other-markets (last accessed June 16, 2022).

- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- Trilogy 100 and 200
- Garbin Plus, Aeris, LifeVent
- A-Series BiPAP Hybrid A30
- A-Series BiPAP V30 Auto
- A-Series BiPAP A40
- A-Series BiPAP A30

13. All of the Recalled Devices are defective because they contain PE-PUR foam.

14. This action arises from Philips' wrongful conduct, including: (a) designing a defective product that exposes users to the risk of serious injury and causes serious injuries to users; (b) failing to warn about serious health risks caused by the Recalled Devices; (c) deliberate concealment, misrepresentation, and obstruction of public and regulatory awareness of serious health risks caused by the Recalled Devices; and (d) failing to use reasonable care in, among other things, designing, testing, manufacturing, marketing, selling, distributing, and recalling the Recalled Devices.[12]

II. THE PARTIES

A. PLAINTIFFS

15. As noted above, there are three master complaints contemplated in this MDL divided, for administrative purposes, into one each for Personal Injury, Medical Monitoring, and Economic Loss. Medical Monitoring Class Plaintiffs identified below are also members of the

[12] Plaintiffs reserve the right to amend this Complaint to reflect additional information uncovered through discovery and developed via expert testimony.

putative class in the Economic Loss Complaint, and do not waive any of their rights or claims as putative class members in that complaint by virtue of serving as proposed Class Representatives for the class or classes proposed in this Medical Monitoring Class Complaint. Furthermore, the parties identified below as Medical Monitoring Class Plaintiffs, in filing this Medical Monitoring Class Complaint, which is limited to medical monitoring per the administrative structure, do not waive, forego, or otherwise relinquish any entitlement they have to economic remedies for all harms incurred as a result of Philips' misconduct and preserve their entitlement to all relief available for the harms alleged.

16. The Medical Monitoring Class Plaintiffs are individuals, each of whom used the Recalled Devices and have suffered injuries from this use.

17. Plaintiff Drew Pendleton ("Pendleton") is a resident of Arizona. Plaintiff acquired a Philips REMStar on or about February 2015, in Washington. Since acquiring the device, Plaintiff has lived in Idaho, Utah, and Arizona. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

18. Plaintiff Russell Autry ("Autry") is a resident of Arkansas. Plaintiff acquired a Philips DreamStation on or about January 2020, in Arkansas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that

Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

19. Plaintiff Deanna Melcher ("Melcher") is a resident of Arkansas. Plaintiff acquired a Philips DreamStation on or about March 2020, in Arkansas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

20. Plaintiff Paul Bailey ("Bailey") is a resident of California. Plaintiff acquired a Philips DreamStation on or about October 2018, in California. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

21. Plaintiff Christine DiJohn ("DiJohn") is a resident of California. Plaintiff acquired a Philips DreamStation on or about September 2008, in California. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

22. Plaintiff Patrick Nielson ("Nielson") is a resident of California. Since acquiring the device, plaintiff has lived in Oregon and California since acquiring the Recalled Devices. Plaintiff acquired a Philips Respironics PR System One REMstar PRO in or about March 2014, in California Plaintiff later acquired another Philips Respironics PR System One REMstar PRO in or about May 2016, in Oregon. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

23. Plaintiff Sylvia McDaniel ("McDaniel") is a resident of Colorado. Plaintiff acquired a Philips DreamStation on or about August 2019, in Colorado. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

24. Plaintiff Jim Wolff ("Wolff") is a resident of Colorado. Plaintiff acquired a Philips DreamStation on or about February 2020, in Colorado. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to

dangerous toxins, he would not have used it.

25. Plaintiff Jill Leavenworth ("Leavenworth") is a resident of Connecticut. Plaintiff acquired a Philips DreamStation on or about May 2020, in Connecticut. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

26. Plaintiff Jose Toscano ("Toscano") is a resident of Connecticut. Plaintiff acquired a Philips DreamStation on or about November 2016, and a second Philips DreamStation on or about November 2020, in Connecticut. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged here. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

27. Plaintiff Jeffrey Boyle ("Boyle") is a resident of Delaware. Plaintiff acquired a Philips DreamStation on or about 2016, in Delaware. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

28. Plaintiff Patricia Ragland ("Ragland") is a resident of the District of Columbia. Plaintiff acquired a Philips REMstar on or about 2012, in the District of Columbia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

29. Plaintiff Tara Fields ("Fields") is a resident of Florida. Plaintiff acquired and used a Philips REMStar CPAP in or around July 2020 in Florida. She used the REMStar until she acquired a Philips DreamStation CPAP on or about September 2020, which she used until at least the date of the Recall. As a result of using the Recalled Devices, Plaintiff suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

30. Plaintiff Dennis Morris ("Morris") is a resident of Florida. Plaintiff acquired a Philips DreamStation CPAP on or about November 2018 in Florida. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

31. Plaintiff Randy Paris ("Paris") is a resident of Florida. Plaintiff acquired a Philips

DreamStation CPAP on or about July 2016, in Florida. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

32. Plaintiff Brian McCarty ("McCarty") is a resident of Hawaii and has lived in Hawaii and Illinois since acquiring the Recalled Devices. Plaintiff has acquired and used three Recalled Devices until at least the date of the Recall. Plaintiff acquired a Philips DreamStation CPAP on or about August 2015 for use in Hawaii, a Philips DreamStation CPAP on or about November 2016, for use in Illinois, and a Philips DreamStation Go on or about November 2016 for use during travel. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

33. Plaintiff Michael Wheeler ("Wheeler") is a resident of Idaho. Plaintiff acquired a Philips DreamStation CPAP on or about December 2018, in Idaho. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device

would cause exposure to dangerous toxins, he would not have used it.

34. Plaintiff Danny Baran ("Baran") is a resident of Illinois. Plaintiff acquired a Philips DreamStation CPAP on or about February 2019, in Illinois. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

35. Plaintiff Debra Wilson ("Wilson") is a resident of Illinois. Plaintiff acquired a Philips DreamStation on or about June 2019, in Illinois. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

36. Plaintiff Michael Dusza ("Dusza") is a resident of Indiana. Plaintiff acquired a Philips DreamStation CPAP on or about June 2016, in Indiana. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

37. Plaintiff Steve Abarr ("Abarr") is a resident of Iowa. Plaintiff acquired a Philips

DreamStation on or about December 2019, in Iowa. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

38. Plaintiff Sharon Cathers ("Cathers") is a resident of Kansas. Plaintiff acquired a Philips DreamStation on or about January 2021, in Kansas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

39. Plaintiff Andrew Fisher ("Fisher") is a resident of Georgia. Since acquiring the device, Plaintiff has lived in Kansas and Georgia. Plaintiff acquired a Philips DreamStation on or about April 2020 in Missouri, while residing in Kansas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

40. Plaintiff Doris Margoles ("Margoles") acquired a Philips DreamStation CPAP on or about 2017 when she resided in Maine. Since 2017, Plaintiff has also lived in North Carolina

and recently moved to Ohio. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

41. Plaintiff Wilbert Cotton ("Cotton") is a resident of Maryland. Plaintiff acquired a Philips DreamStation on or about March 2020 in Maryland. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

42. Plaintiff Quinton Goodall ("Goodall") is a resident of Maryland. Plaintiff acquired a Philips DreamStation on or about August 2016, in Maryland. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

43. Plaintiff Peter Bellotti ("Bellotti") is a resident of Massachusetts. Plaintiff acquired a DreamStation Auto CPAP on or about September 2017, in Massachusetts. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently

suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

44. Plaintiff Prinna Boudreau ("Boudreau") is a resident of Minnesota. Plaintiff acquired a Philips DreamStation on or about 2019, and a Philips System One on or about 2011, both in Minnesota. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

45. Plaintiff John Young ("Young") is a resident of Missouri. Plaintiff acquired a SystemOne in or about August 2013, and a DreamStation in or about January 2021, both in Missouri. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

46. Plaintiff Danny David ("David") is a resident of Montana. Plaintiff acquired a Philips DreamStation on or about January 2021, in Montana. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure

to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

47. Plaintiff Boniface Mills ("Mills") is a resident of Nebraska. Plaintiff acquired a DreamStation in or around 2015, in Nebraska. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

48. Plaintiff Christopher Glaub ("Glaub") is a resident of Nebraska. Plaintiff acquired a REMStar Pro in or about 2013, in Nebraska. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

49. Plaintiff Elizabeth Lemus ("Lemus") is a resident of Nevada. Plaintiff acquired a DreamStation in or about September 2017, in Nevada. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop

cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

50. Plaintiff Sabrina Malone ("Malone") is a resident of New Hampshire. Since acquiring the device, plaintiff has lived in Texas and New Hampshire. Plaintiff acquired a DreamStation Auto CPAP in or about December 2017, in Texas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

51. Plaintiff Aaron Taylor ("Taylor") is a resident of New Jersey. Plaintiff acquired a DreamStation CPAP in or about late 2015 or early 2016, in New Jersey. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

52. Plaintiff Joe David Dennett is a resident of New Mexico. Plaintiff acquired a Philips DreamStation on or about September 2019 in New Mexico. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to

dangerous toxins, he would not have used it.

53. Plaintiff Beth Rodgers ("Rodgers") is a resident of Virginia. Since acquiring her devices, Plaintiff has resided in Virginia and New Mexico. Plaintiff acquired a SystemOne in or about 2013, in New Mexico, and later acquired a DreamStation in or about June 2019, in Virginia. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

54. Plaintiff Hugo Barragan ("Barragan") is a resident of New York. Plaintiff acquired a DreamStation in or about October 2020, in New York. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

55. Plaintiff Sonia Diaz ("Diaz") has resided in New York and South Carolina since acquiring her Recalled Device. Plaintiff acquired a Philips DreamStation Auto CPAP in or about October 2016 in New York. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other

diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

56. Plaintiff Bruce Ginsberg ("Ginsberg") is a resident of New York. Plaintiff acquired a Philips DreamStation CPAP on or about 2018, in New York. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

57. Plaintiff Deana King ("King") is a resident of North Carolina. Plaintiff acquired a DreamStation Auto BiPAP in or about April 2016, in North Carolina. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

58. Plaintiff Jeffrey Bartalo ("Bartalo") is a resident of North Carolina. Plaintiff acquired a Philips DreamStation in or about December 2019, in North Carolina. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

59. Plaintiff Rachel Hock ("Hock") is a resident of Ohio. Plaintiff acquired a Philips System One on or about 2014, and a Philips DreamStation CPAP on or about November 2018, both in Ohio. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

60. Plaintiff Chad Wells ("Wells") is a resident of Oklahoma. Plaintiff acquired a Philips SystemOne BiPAP/BiFLEX in or about August 2012, in Oklahoma. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

61. Plaintiff Arthur Hibbard ("Hibbard") is a resident of Pennsylvania. Plaintiff acquired Philips REMStar devices beginning in or about 2008, and continued to use them through 2021. Plaintiff later acquired a Philips DreamStation in or about March 2021. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

62. Plaintiff Joseph Hoffman ("Hoffman") is a resident of Pennsylvania. Plaintiff acquired a Philips REMStar in or about October 2015, in Pennsylvania. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

63. Plaintiff Marilyn Sweeney ("Sweeney") is a resident of Pennsylvania. Plaintiff acquired a Philips DreamStation in or about January 2019 and a Philips DreamStation Go in or about February 2019, in Pennsylvania. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

64. Plaintiff Antonio Perez Bonano ("Bonano") is a resident of Puerto Rico. Plaintiff acquired a Philips DreamStation in or about April 2019, in Puerto Rico. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

65. Plaintiff Diane Lamontagne ("Lamontagne") is a resident of Rhode Island. Plaintiff

acquired a Philips DreamStation in or about March 2016, in Rhode Island. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

66. Plaintiff Stephen Flannery ("Flannery") is a resident of South Carolina. Plaintiff acquired a DreamStation on or about February 2018, in South Carolina. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

67. Plaintiff Susan Bakaitis ("Bakaitis") is a resident of Tennessee. Plaintiff acquired a Philips DreamStation CPAP on or about December 2020 in Tennessee. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

68. Plaintiff Jeffrey Kemp ("Kemp") is a resident of Tennessee. Plaintiff acquired a Philips DreamStation Auto CPAP in or about 2017, in Tennessee. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered

exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

69. Plaintiff Sarah Claunch ("Claunch") is a resident of Texas. Plaintiff acquired a Philips DreamStation CPAP on or about 2018, in Texas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

70. Plaintiff Paul Panzera ("Panzera") is a resident of Texas. Plaintiff acquired a Philips DreamStation in or about June 2018, in Texas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

71. Plaintiff Martin Humphries ("Humphries") is a resident of Utah. Plaintiff acquired a Philips SystemOne ASV4 in or about 2014, in Utah. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop

cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

72. Plaintiff David Martin ("Martin") is a resident of Vermont. Plaintiff acquired a Philips REMStar in or about 2011, and a Philips DreamStation in or about June 2016, in Vermont. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

73. Plaintiff Madaline Harbor ("Harbor") is a resident of Virginia. Plaintiff acquired a Philips DreamStation on or about August 2016, in Virginia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

74. Plaintiff Elizabeth Heilman ("Heilman") is a resident of Virginia. Plaintiff acquired a Philips DreamStation in or about 2018, in Virginia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

75. Plaintiff Cameron Rose ("Rose") is a resident of Virginia. Plaintiff acquired a Philips DreamStation in or about May 2018, in Virginia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

76. Plaintiff Jose Lopez ("Lopez") is a resident of Washington. Plaintiff acquired a Philips DreamStation in or about October 2019, in Washington. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

77. Plaintiff Robert Peebles ("Peebles") is a resident of Washington. Plaintiff acquired a Philips DreamStation in or about October 2020, in Washington. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

78. Plaintiff Dennis Caling ("Caling") is a resident of West Virginia. Plaintiff acquired a Philips DreamStation CPAP on or about July 2019, in West Virginia. Plaintiff has used the

Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

79. Plaintiff Brent Hamlin ("Hamlin") is a resident of West Virginia. Plaintiff acquired a DreamStation in or about December 2019, in West Virginia. Plaintiff has used the Recalled Device[s] since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

80. Plaintiff Donald Rucker ("Rucker") is a resident of West Virginia. Plaintiff acquired a Philips DreamStation on or about September 2019, and then acquired a second DreamStation in 2020, both in West Virginia. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

B. DEFENDANTS

81. Defendant Koninklijke Philips N.V. ("Royal Philips") is a Dutch multinational company having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of the Philips group of

healthcare technology businesses including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries, Philips North America LLC and Philips RS North America LLC.[13] As such, Royal Philips controls Philips North America LLC and Philips RS North America LLC with respect to the manufacturing, selling, distributing, and supplying of the Recalled Devices.[14]

82. Defendant Philips North America LLC ("Philips NA") is a Delaware company with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips. Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS North America LLC, in North America. The sole member of Philips NA is Philips Holding USA Inc. Philips NA is 100% owned by Philips RS North America Holding Corporation which, in turn, is 100% owned by Philips Holding USA Inc.

83. Defendant Philips Holding USA Inc. ("PHUSA") is a Delaware corporation with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is 100% owned, directly or indirectly, by Royal Philips. PHUSA owns 100% of Philips RS North America LLC and Philips RS North America Holding Corporation, and is the member/manager of Philips NA.

84. Defendant Philips RS North America LLC ("Philips RS") is a Delaware company with its principal place of business at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips

[13] Philips 2020 annual filing with the SEC, fn. 8, https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (last accessed June 16, 2022).

[14] Philips 2020 annual filing with the SEC, https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (last accessed June 16, 2022).

RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[15] Philips RS is 100% owned by Philips RS North America Holding Corporation, which in turn, is 100% owned by PHUSA.

85. Defendant Philips RS North America Holding Corporation ("Philips RS Holding") is a Delaware corporation with its principal place of business at 222 Jacobs Street, Cambridge, Massachusetts 02141, and is wholly owned by PHUSA. Accordingly, Philips RS Holding is a citizen of Massachusetts and Delaware.

86. At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and reference to "Philips" refers to each Philips Defendant individually and collectively.

87. Defendant Polymer Technologies, Inc. ("Polymer Tech") is a Delaware corporation with its principal place of business at 420 Corporate Blvd, Newark, DE 19702. Polymer Tech directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

88. Defendant Polymer Molded Products LLC ("PMP") is a Delaware corporation with its principal place of business at 10 Easy Street, Bound Brook, NJ 08805. PMP is a molded polyurethane foam manufacturer. PMP directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

89. Defendant Polymer Technologies, Inc. Elastomeric Solutions Division ("ESD") is a Delaware corporation with its principal place of business at 76 Astor Ave #101, Norwood, MA 02062. ESD specializes in shock and vibration isolation materials for products including medical

[15] Philips announces completion of tender offer to acquire Respironics, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (last accessed June 16, 2022).

devices. ESD directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

90. At all relevant times, Defendants Polymer Tech, PMP, and ESD acted in all respects as the agent and alter ego of one another, and reference hereinafter to "PolyTech" or the "PolyTech Defendants" refers to Defendants Polymer Tech, PMP, and ESD individually and collectively.

91. Other Defendants may be named in the Short Form Complaints.

III. JURISDICTION AND VENUE

92. The Court has subject matter jurisdiction under 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which Plaintiffs and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).

93. Each Philips Defendant has significant contacts with the Western District of Pennsylvania such that they are subject to the personal jurisdiction of the Court.

94. This Court has personal jurisdiction over each Philips Defendant for the additional reason that they have engaged in substantial, systematic and continuous contacts with Pennsylvania by, *inter alia*, regularly conducting and soliciting business in Pennsylvania and this District, deriving substantial revenue from products and/or services provided to persons in Pennsylvania and this District.

95. Venue is proper in this District on account of the MDL designation pursuant to 28 U.S.C. § 1407 and under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this District.

IV. FACTUAL ALLEGATIONS

A. CPAP AND BIPAP MACHINES AND VENTILATORS ARE PRESCRIBED TO TREAT BREATHING DISORDERS.

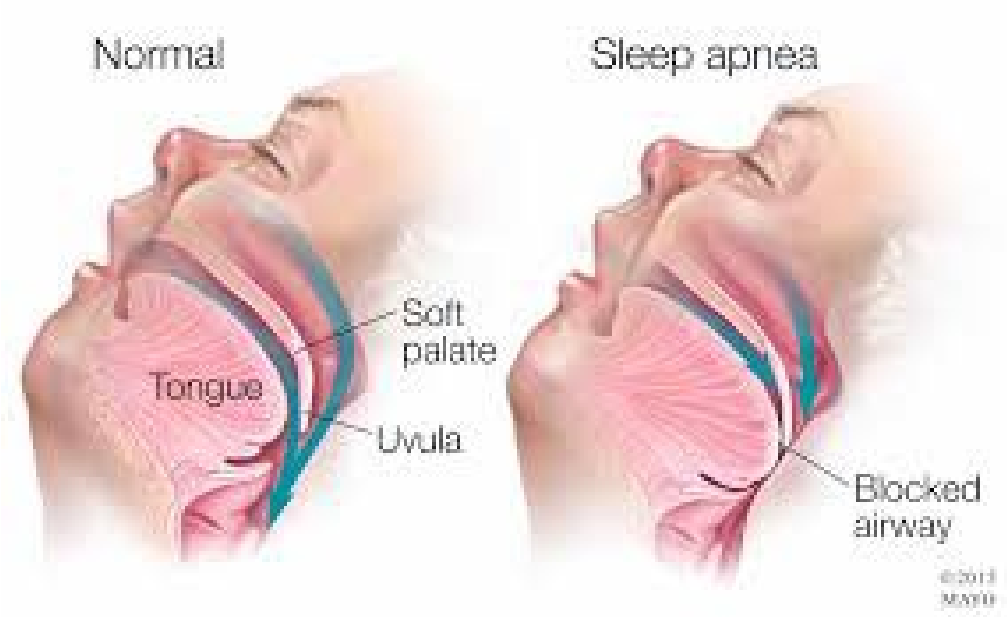
96. Sleep apnea is a sleeping disorder in which breathing is disturbed during sleep. These disturbances are called "apneas."

97. According to the Mayo Clinic, the main types of sleep apnea are obstructive sleep apnea, central sleep apnea, and complex sleep apnea syndrome (also known as treatment-emergent central sleep apnea).

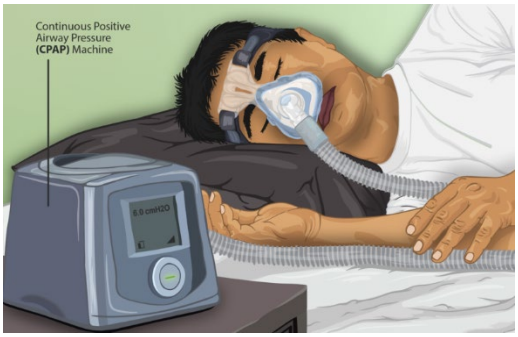
98. Obstructive sleep apnea is the most common type of sleep apnea. It occurs when the muscles in the back of the throat relax during inhalation, which causes the airway to narrow or close and prevent sufficient air from passing through. This in turn lowers the oxygen level in the blood, which causes the brain briefly to wake the body from sleep to reopen the airway. This reawakening may be so brief that the patient does not remember it, and it may be associated with snorting, choking, or gasping. It can happen anywhere from a few times per hour to once every few minutes, and can prevent the patient from reaching the deep, restful phases of sleep.

99. Central sleep apnea occurs when the brain fails to transmit signals to the breathing muscles. As a result, the body stops breathing, which can cause waking with shortness of breath, difficulty getting to sleep, or difficulty staying asleep.

100. Complex sleep apnea syndrome occurs when a patient has both obstructive sleep apnea and central sleep apnea. An image showing how an airway can be blocked as a result of sleep apnea appears below:

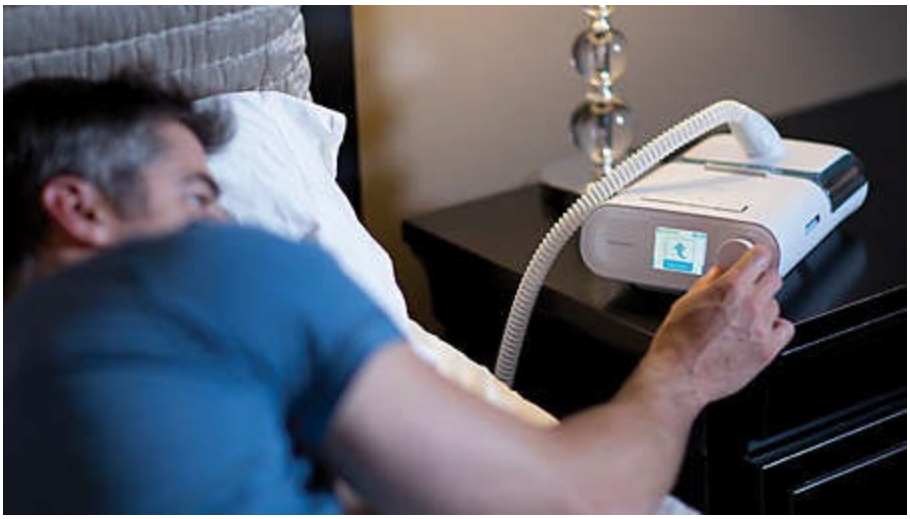


101. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a continuous flow of air through a mask that is placed over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea. The illustration below shows a generic CPAP machine being used by a patient while sleeping.

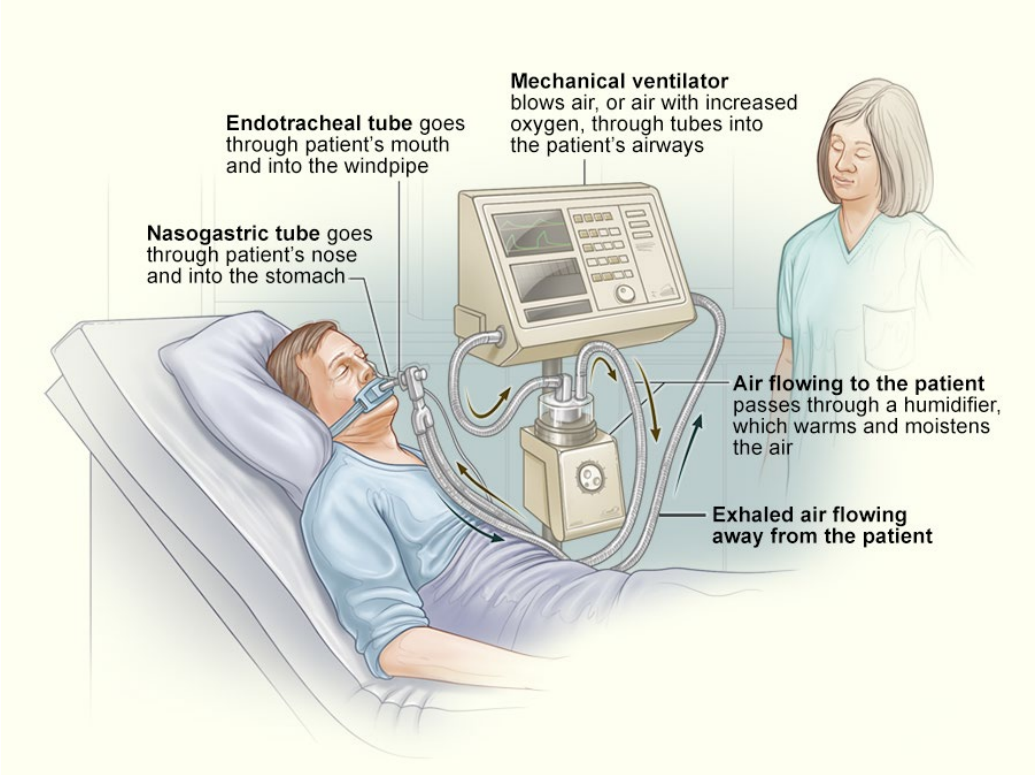


102. Another therapy to treat sleep apnea includes use of BiPAP machines, which use two different pressures – one for inhaling and one for exhaling.

103. Patients customarily place CPAP or BiPAP machines on a nearby nightstand or shelf. A hose connects the unit to a mask, which is worn over the nose or mouth during sleep. Below is an image of a Philips DreamStation machine on a nightstand.



104. Ventilators are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows, typically through a tube that is connected to the machine on one end and inserted through the patient's nose or mouth into the trachea on the other end. Patients are typically sedated while on ventilation because it can otherwise cause intense pain. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. There are also ventilators for home use. The following image from the National Institute of Health ("NIH") shows a typical ventilator and how it works:



B. THE EVOLUTION OF CPAP, BIPAP, AND VENTILATOR DEVICES CONTAINING PE-PUR FOAM.

105. The basic technology used in CPAP and BiPAP devices was developed in 1980 by an Australian pulmonologist, Dr. Colin Sullivan, who used it to treat dogs with respiratory problems, before the technology was adapted for humans.

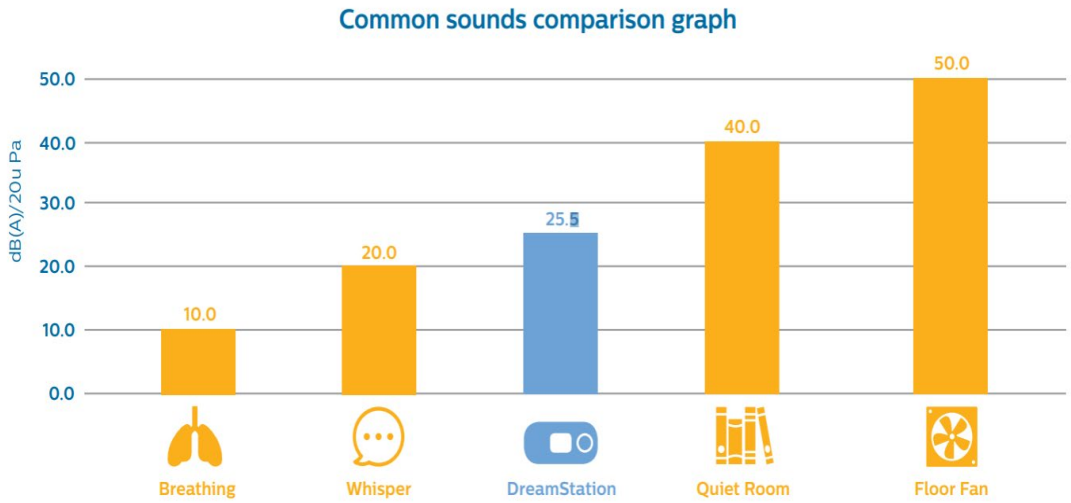
106. Respironics commercialized this technology and sold the first publicly available CPAP device in 1985. ResMed, an industry competitor, followed with the release of its CPAP device in 1989.

107. These first-generation CPAP and BiPAP devices created a new and commercially viable field of respiratory therapy. The devices, however, were large and noisy, resulting in an "arms-race" between manufacturers to develop devices that were smaller, more responsive to patient breathing patterns, and quieter.

108. The noise level of CPAP and BiPAP devices became a driver of adult consumer preference because loud devices interrupted the peaceful sleep of both the patient and their partner.

109. To develop the quietest devices on the market with the lowest decibel ratings, some device manufacturers including Philips filled the CPAP, BiPAP, and ventilator devices with sound abating foam to reduce the volume of noise emitted from the devices.

110. In fact, the alleged relative quiet nature of the DreamStation products with PE-PUR foam factored prominently into Philips' marketing. [16] Philips represents that it extensively studied and measured the amount of sound produced by DreamStation products. Philips even included an infographic indicating DreamStation products are barely louder than a whisper:[17]



111. Other manufacturers did not utilize foam for sound abatement, instead they utilized silencing technology to abate the sound from the devices.

[16] *See* https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf (last accessed Aug. 15, 2022).

[17] *See id*. at 3.

112. Philips manufactures and sells CPAP and BiPAP machines and ventilators, among other products. According to Royal Philips' 2020 Annual Report,[18] Sleep & Respiratory Care constituted 49% of its total sales in its Connected Care line of business, which, in turn, accounted for 28% of Royal Philips' overall sales of about €19.535 billion. Philips has sold millions of CPAP, BiPAP, and ventilator devices in the United States and elsewhere throughout the globe.

113. Philips provides a User Manual with its CPAP, BiPAP, and ventilator devices. Royal Philips owns the copyright to all, or most, of those User Manuals.[19]

114. Philips made the decision to use PE-PUR foam for sound abatement purposes in its CPAP, BiPAP, and ventilator devices. That decision was made for products distributed by Philips' entities throughout the globe including, but not limited to the United States, Australia, Canada, Israel, and Chile.[20]

115. Polyurethane is an organic polymer in which urethane groups connect the molecular units. It is usually formed by reacting a diisocyanate or triisocyanate with a polyol. Under certain circumstances, polyurethane may break down into a diisocyanate or triisocyanate.

116. The two main types of polyurethane are polyester and polyether. Polyester polyurethane has better shock absorption and vibration dampening properties and is commonly used for soundproofing or sound dampening.

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[18] *See* Philips' 2020 Annual Report, available at https://www.results.philips.com/publications/ar20?type=annual-report&origin=2_us_en_5250933_Microsoft+Shopping+%28Bing+Rebates%2C+Coupons%2C+etc.%29_mixedtype_cj&utm_source=5250933&utm_medium=affiliate&utm_campaign=cj&cjevent=ec08e4671a4811ed838f01650a82b821&utm_term=Microsoft+Shopping+%28Bing+Rebates%2C+Coupons%2C+etc.%29&cjdata=MXxOfDB8WXww (last accessed Aug. 15, 2022).

[19] *See, e.g.*, Warranty Exemplars: DreamStation (attached hereto as Exhibit "B-1"); REMstar SE (attached hereto as Exhibit "B-2"); Trilogy 100 (attached hereto as Exhibit "B-3").

[20] *See* Philips Q2 2022 Results, pg. 33, available for download at Philips Q2 2022 Quarterly Results | Philips Results. (last accessed Aug. 15, 2022)

117. It has been known for decades that polyester polyurethane is susceptible to hydrolysis, the chemical breakdown of a compound due to reaction with water, particularly in medical applications. For example, a chapter of a scientific encyclopedia published in 2013 states: "Poly(ester urethanes) were the first generation of PURs used in medical devices but were found unsuitable for long-term implants because of rapid hydrolysis of the polyester soft segment[.]"[21]

118. Polyether polyurethane, on the other hand, is less prone to hydrolysis. The same scientific encyclopedia chapter notes that polyether polyurethanes "with excellent hydrolytic stability replaced poly(ester urethanes) and have been used in medical devices for the past two decades."[22]

119. There were readily available alternative designs available to Philips, other than to use PE-PUR foam in CPAP, BiPAP, and ventilator devices for sound abatement. These include, for example, other types of sound abating foam and silencing technologies that do not use foam.

120. For example, Philips' principal competitor, ResMed, uses polyether polyurethane foam or silicone-based foam, not PE-PUR foam, for sound dampening.[23]

C. PHILIPS SOUGHT CLEARANCES FROM THE FDA TO MARKET CPAP, BIPAP, AND VENTILATOR DEVICES THAT IT DESIGNED AND MANUFACTURED.

121. Philips designed and manufactured CPAP and BiPAP devices and ventilators, including the Recalled Devices.

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[21] Pal Singh Chauhan, N., and Kumari Jangid, N., "Polyurethanes and Silicone Polyurethane Copolymers," Chapter in Encyclopedia of Biomedical Polymers and Polymeric Biomaterials, January 2013, *available at* https://www.researchgate.net/publication/236144965_POLYURETHANES_AND_SILICONE_POLYURETHANE_COPOLYMERS (last accessed Aug. 12, 2022).

[22] *Id.*

[23] https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Aug. 12, 2022).

122. Defendants obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various CPAP, BIPAP and ventilator devices.

123. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

124. 510(k) clearance generally only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

125. Philips utilized the 510(k) process to receive clearances for each of its Recalled Devices except the E30 ventilator which was marketed under an Emergency Use Authorization (EUA).

126. With respect to the EUA for the E30 ventilator, on March 24, 2020, in response to "concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in healthcare settings to treat patients during the Coronavirus Disease 2019 (COVID-19) pandemic[,]" the FDA issued an umbrella EUA of ventilators and related equipment. On April 8, 2020, this EUA was extended to the E30 ventilator. A device may be authorized under this umbrella EUA if it "may be effective" in diagnosing, treating, or preventing COVID-19; and according to the FDA, "[t]he 'may be effective' standard for EUAs provides for a lower level of evidence than the 'effectiveness' standard that FDA uses for product approvals."

127. With respect to the 510(k) process for each of the other Recalled Devices, Philips included data, testing, and biocompatibility results along with its applications to claim substantial equivalence to a predicate device

128. Upon reviewing the submissions, the FDA determined Philips' devices were substantially equivalent to a predicate device.

129. After the devices were sold, Philips had a duty to find, investigate, and report adverse events to the FDA. For example, 21 C.F.R. part 803 requires Philips to conduct a thorough investigation of each event. This duty is triggered when Philips becomes aware of information from any source that reasonably suggests that its device (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned, and, this device or a similar device it markets, is likely to cause or contribute to a death or serious injury, if the malfunction were to recur. 21 C.F.R. § 803.50.

130. Additionally, as a manufacturer, Philips has unique knowledge concerning the frequency, severity and predictability of the complications and risks associated with its devices. Accordingly, Philips has post-market responsibility under the FDA Regulations related to complaint handling, investigation and reporting to the FDA, including but not limited to:

a. 21 C.F.R. § 803.10 (for example, § 803.10(c) requires adverse events to be reported by a manufacturer in set time frames from 5 to 30 days when the event becomes known);

b. 21 C.F.R. § 803.17 ("Medical device manufacturers must develop and implement standardized medical device reporting procedures so that timely evaluation of events and communication of findings can occur.");

c. 21 C.F.R. § 803.18 (§ 803.18(d)(1) requires a device distributor to maintain complaint files and records, including any written, electronic or oral communication, either received or generated by the distributor, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device.);

d. 21 C.F.R. § 803.20 ("Manufacturers must timely communicate a reportable event. Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.");

e. 21 C.F.R. § 803.3 ("If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.");

f. 21 C.F.R. § 803.50 ((a) "If you are a manufacturer, you must report to the FDA information required by 803.52 in accordance with the requirements of 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." Subsection (b) defines information reasonably known to a manufacturer to include: "[a]ny information that you can obtain by contacting a user facility, importer, or other initial reporter; . . . [a]ny information in your possession; or . . . [a]ny information that you can obtain by analysis, testing, or other evaluation of the device." Section 803.50 continues: "(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).");

g. 21 C.F.R. § 803.52 (detailed individual and device information must be submitted for each adverse event);

h. 21 C.F.R. § 803.53 (information regarding detailed individual and device information must be submitted in a timely manner when remedial action may be required);

i. 21 C.F.R. § 803.56 (supplemental reporting must be done if additional information is learned that became known after the initial report was submitted);

j. 21 C.F.R. § 814.82(a)(2) (manufacturer has a duty of "[c]ontinuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted.");

k. 21 C.F.R. § 814.84 (the periodic reports required by law must contain the reports in the scientific literature that pertain to the device which are known or should be known to the manufacturer); and

l. 21 C.F.R. § 820.198 ("Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event").

131. In addition, there are state law duties to monitor, investigate, evaluate and timely report injuries and other important safety information regarding a medical device, which Philips violated when it failed to: monitor, investigate and report PE-PUR foam degradation risk and incidents; take the necessary steps to continually evaluate the safety, effectiveness and reliability of its Recalled Devices; and take necessary steps to warn, strengthen its warnings, and take other measures to assure compliance with its obligations.

D. PE-PUR FOAM POSES A SERIOUS HEALTH RISK TO USERS OF PHILIPS DEVICES.

132. Philips has belatedly revealed that the PE-PUR foam in the Recalled Devices degrades and exposes patients to toxic particles and gases. Such exposure has harmed hundreds of thousands of patients across the United States who used the Recalled Devices.

133. On the same day as the Recall, Philips released an announcement entitled "Clinical information for physicians." In this announcement, Philips disclosed that it "has received several

complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[24] The PE-PUR foam is black, and when it breaks down, it can release black particles.[25] The announcement stated that the foam breakdown "may lead to patient harm and impact clinical care,"[26] explaining:

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, ***it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.***[27]

134. The announcement mentioned two types of hazards from the foam in the devices: dangers from foam degradation and dangers from release of VOCs.

135. First, the announcement described dangers arising from foam degradation exposure:

> **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> - Toluene Diamine

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[24] Sleep and respiratory care update: Clinical information for physicians: philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Aug. 15, 2022).

[25] *Id.*

[26] *Id.*

[27] *Id.* (emphasis added).

- Toluene Diisocyanate

- Diethylene glycol.[28]

136. The inhalation of extremely fine particulates, even non-toxic particulates, can lead to adverse health outcomes. The Environmental Protection Agency ("EPA") notes that exposure to particles less than 10 micrometers can be linked to a variety of health problems including: aggravated asthma, decreased lung function, increased respiratory symptoms, and cardiac related diseases."[29]

137. On July 8, 2021, Philips released a global supplemental clinical information document that contained results based on its own testing of the affected devices, stating that: "According to analysis performed by Philips, the majority of particulates are of a size (>8 µm) . . . Smaller particulates (<1-3 µm) are capable of diffusing into deep lung tissue and deposit into the alveoli. During testing performed by an outside laboratory on lab degraded foam, the smallest particulate size identified was 2.69 µm."[30]

138. The purity of the air coming from a breathing device to a patient is highly important and material. Indeed, Philips advertises the filtration systems in its devices, for example, noting them on a diagram in its DreamStation Family Brochure.[31] Philips' filtration system, however, does not filter out the particles described above.

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[28] *Id*.

[29] *See* Health and Environmental Effects of Particulate Matter (PM) | US EPA. (last accessed Aug. 15, 2022).

[30] *See* philips-global-supplemental-clinical-information-document.pdf.

[31] https://www.documents.philips.com/assets/20180205/15ef65ad106d4ddc88fca87e0134dc60.pdf?_gl=1*1l6jo9f*_ga*MTM1OTI5NDM5Ny4xNjIzODE3MzMz*_ga_2NMXNNS6LE*MTYyNjkxMDEyNC4yMi4xLjE2MjY5MTQyNTkuMjc.&_ga=2.220564312.1106063144.1626914226-1359294397.1623817333 (last accessed Aug. 15, 2022).

139. In addition to the hazards created by the inhalation of extremely fine particulates, Philips has admitted that the particulates created via PE-PUR foam degradation contain toxic compounds such as toluene diamine, toluene diisocyanate, and diethylene glycol.[32] As discussed in more detail below, these compounds are toxic and/or carcinogenic when inhaled or ingested.

140. Philips concluded in its Health Hazard Evaluations ("HHEs") regarding the PE-PUR foam degradation risk that "[b]ased on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with [the] conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track [*sic*], a reasonable worst-case estimate for the general and higher risk (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure."[33]

141. Philips' HHEs note that the harm due to foam degradation "'may not be immediately recognizable and may not be something that the customer would/could report,' adding that certain harms 'may not be easily linked to the hazardous situation or device use in general'—and that in the case of genetic mutations in particular, 'a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage.'"[34]

142. The second hazard is the release of VOCs, that is, toxic and carcinogenic chemical emissions from the PE-PUR foam. Philips explained:

> **Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam

[32] *See* philips-global-supplemental-clinical-information-document.pdf.

[33] 518(b) Notice at 3-4.

[34] *Id.* at 5.

> included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:
>
> - Dimethyl Diazine
>
> - Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl).[35]

143. In addition to these two compounds, Philips has also found high levels of formaldehyde, a known carcinogen, in analyses of the Recalled Devices. Collectively, these compounds released by PE-PUR foam—formaldehyde, toluene diamine, toluene diisocyanate, diethylene glycol, dimethyl diazine, and phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)—are referred to herein as the "Foam Toxins."

144. Philips admitted that the risks of these VOCs include: "irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."[36]

145. It is beyond reasonable dispute that patients using the Recalled Devices were exposed to harmful particulates and the toxic Foam Toxins. As detailed below, each of the Foam Toxins poses a serious health hazard to users of the Recalled Devices.

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[35] *See* philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Aug. 15, 2022).

[36] *Id.*

1. Formaldehyde Is A Known Carcinogen.

146. Although Philips has not publicly acknowledged that formaldehyde is used in the manufacturing process for PE-PUR foam or is a byproduct of PE-PUR foam degradation, Philips' internal testing (dated May 22, 2019) reported the presence of formaldehyde in analyses of its DreamStation 1 devices, finding "tolerable limits of the Formaldehyde compound were exceeded during initial operation, as well as at the [redacted]."[37]

147. Formaldehyde has been classified as carcinogenic to humans (Group 1)[38] by the International Agency for Research on Cancer ("IARC") since 2006.[39] Governmental authorities in the United States have reached similar conclusions: the National Toxicology Program in the United State Department of Health and Human Services ("NTP") has classified formaldehyde as a known human carcinogen since 2011[40]; and the EPA has considered formaldehyde to be a probable human carcinogen (Group B1) since 1989.[41]

148. There is extensive research, including dozens of human epidemiological studies,

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[37] *See* 483 Report at 6.

[38] The IARC, an agency of the World Health Organization, groups carcinogenic and potentially carcinogenic substances into five categories: Group 1, carcinogenic to humans; Group 2A, probably carcinogenic to humans; Group 2B, possibly carcinogenic to humans; Group 3, not classifiable as to its carcinogeneity to humans; and Group 4, probably not carcinogenic to humans. International Agency for Research on Cancer, *Agents Classified by the IARC Monographs, Volumes 1–129*, IARC (last updated Jul. 1, 2022), *available at* http://monographs.iarc.fr/ENG/Classification/index.php. The EPA uses an equivalent grouping system of five categories (Groups A-E). *See Risk Assessment for Carcinogenic Effects*, EPA.com, *available at* https://www.epa.gov/fera/risk-assessment-carcinogenic-effects.

[39] *Formaldehyde*, IARC Monograph – 100F, IARC, *available at* https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono100F-29.pdf .

[40] *Formaldehyde*, Report on Carcinogens, NTP, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf.

[41] *See* https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet#r1 (last accessed Aug. 15, 2022).

showing an association between formaldehyde exposure and numerous forms of cancer, including: nasopharyngeal cancer; sinonasal cancer; leukemia; lung cancer; lymphohematopoietic cancers (other than leukemia); nasal, oral, and throat cancers (other than nasopharyngeal and sinonasal cancers); brain cancer; hepatic cancer; esophageal cancer; thyroid cancer; and pancreatic cancer.[42] Additionally, exposure to formaldehyde appears to have a strong causal relationship to asthma.[43]

2. Toluene Diisocyanate Is A Likely Carcinogen.

149. Toluene diisocyanates ("TDIs") are used primarily to manufacture flexible polyurethane foams such as PE-PUR foam. Philips has recognized that PE-PUR foam releases TDIs as it degrades.[44]

150. TDI is classified as possibly carcinogenic to humans (Group 2B) by IARC.[45] The United States Center for Disease Control ("CDC"), Occupational Safety and Health Administration ("OSHA"), and National Institute for Occupational Safety and Health ("NIOSH") also regard TDI as a potential human carcinogen based on tumorigenic responses in TDI treated rats and mice.[46] The EPA has taken action under the Toxic Substances Control Act to allow

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[42] *See, e.g.*, *Formaldehyde*, Report on Carcinogens, NTP, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf; *1910.1048 App C - Medical surveillance – Formaldehyde*, OSHA.com, *available at* https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048AppC. (last accessed Aug. 15, 2022).

[43] *See, e.g.*, *1910.1048 App C - Medical surveillance – Formaldehyde*, OSHA.com, *available at* https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048AppC.

[44] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf ("[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include … toluene diisocyanate isomers (TDI)").

[45] *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, *available at*, https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf. (last accessed Aug. 15, 2022).

[46] *See, e.g.*, *Toluene diisocyanates*, Report on Carcinogens, NTP, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf; *Current Intelligence*

oversight of the use of TDI in consumer products.[47] NTP classifies TDI as "reasonably anticipated to be a human carcinogen" based on sufficient evidence of carcinogenicity from studies in experimental animals.[48] The European Union warns that TDI "is fatal if inhaled."[49]

151. Administration of TDI by stomach tube caused liver tumors (hepatocellular adenoma) in female rats and mice, benign tumors of the mammary gland (fibroadenoma) and pancreas (islet-cell adenoma) in female rats, and benign tumors of the pancreas (acinar-cell adenoma) in male rats. It also increased the combined incidences of benign and malignant tumors of subcutaneous tissue (fibroma and fibrosarcoma) in rats of both sexes and of the blood vessels (hemangioma and hemangiosarcoma) in female mice.[50] Exposure to TDI also has been documented to cause respiratory irritation, asthma, and lung damage.[51]

3. Toluene Diamine Is A Likely Carcinogen.

152. Philips has recognized that PE-PUR foam releases toluene diamine ("TDA") as it degrades.[52] Additionally, TDA is a hydrolysis product of TDI.

Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity, NIOSH Pub. No. 90-101 (Dec. 1989), *available at* https://www.cdc.gov/niosh/docs/90-101/default.html. (last accessed Aug. 15, 2022).

[47] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-toluene-diisocyanate-tdi-and-related#action.

[48] *See* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf (last accessed Aug. 17, 2022).

[49] https://echa.europa.eu/substance-information/-/substanceinfo/100.043.369 (last accessed Aug. 15, 2022, 2022).

[50] *See* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf. (last accessed Aug. 15, 2022).

[51] *See, e.g.*, *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, *available at*, https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf.

[52] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf ("[T]he degradative by-products of a

153. IARC has classified TDA as possibly carcinogenic to humans (Group 2B),[53] and the EPA classifies it as a probable human carcinogen.[54] The European Union has concluded that TDA "cannot be considered safe for use" even as a hair dye, let alone breathed into the lungs for many hours each night.[55] The NTP classifies TDA as reasonably anticipated to be a human carcinogen based on animal studies.[56]

154. Available data on TDA primarily comes from animal studies. These studies strongly support an association between TDA and hepatic cancer.[57] There is evidence of a link between TDA exposure and pulmonary fibrosis based on in vitro studies in which human lung fibroblasts were exposed to TDI and TDA.[58] The EPA has determined that acute exposure to TDA can produce severe skin and eye irritation, sometimes leading to permanent blindness, respiratory

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PE-PUR foam after a humid ageing experiment were found to include … toluene diamine isomers (TDA)").

[53] *See Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, *available for download at*, https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf.

[54] *See Toluene 2,4 diamine*, EPA (Jan. 2000), *available at* https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf.

[55] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_093.pdf (last accessed Aug. 15, 2022), at 5.

[56] *2,4-Diaminotoluene*, Report on Carcinogens, NTP, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/diaminotoluene.pdf.

[57] *Id.*

[58] It is well established that TDI is converted to TDA through hydrolysis (a reaction caused by exposure to water). *See Current Intelligence Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, NIOSH Pub. No. 90-101 (Dec. 1989), *available at* https://www.cdc.gov/niosh/docs/90-101/default.html. Thus, ingested TDI may react with saliva and/or gastrointestinal fluids and convert to TDA. Additionally, there is evidence that inhaled TDI is converted into TDA by reaction with a substance (gluthathione) present in the lungs. As a result, observed effects ascribed to TDI may be due to unmeasured conversion to TDA after exposure.

problems (*e.g.*, asthma), rise in blood pressure, dizziness, convulsions, fainting, and coma.[59] Exposure to TDA can also cause irritation of the skin, nose, and throat, damage to reproductive and neurological systems, eye irritation, dermatitis, ataxia, tachycardia, respiratory depression, stomach gas, hypertension, nausea, vomiting, methemoglobinemia, cyanosis, headache, weakness, exhaustion, dizziness, convulsions, fainting, and coma.[60]

4. Diethylene Glycol Is Toxic To Humans.

155. Diethylene glycol ("DEG") is a widely used solvent. It is a colorless and odorless liquid with a sweetish taste and has often been a contaminant in consumer products, resulting in numerous epidemics of poisoning. DEG is used in the production of polyester polyurethane foam, and Philips has admitted that DEG is a byproduct of PE-PUR foam degradation.[61]

156. DEG has a historical involvement in mass poisonings around the world. Famously, DEG caused the death of 100 people across 15 states in the 1937 Elixir Sulfanilamide Incident, which served as a catalyst for the enactment of the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1938.[62]

157. DEG is a toxic substance with a mean fatal dose of 1 mL/kg of pure DEG.[63]

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[59] *Id.*

[60] *See Toluene 2,4 diamine*, EPA (Jan. 2000), *available at* https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf.

[61] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf ("[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include diethylene glycol (DEG) … .").

[62] https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf (last accessed Aug. 15, 2022).

[63] L.J. Schep, *et al*., *Diethylene glycol poisoning*, Clin. Toxicol. 47(6):525-35 (Jul.2009).

Ingesting only a small amount may result in gastrointestinal distress and stupor.[64] Exposure may cause irritation of the eyes, skin, and mucous membranes.[65] DEG has also been shown to have damaging toxic, irritating, and inflammatory properties when inhaled.[66]

5. Dimethyl Diazine Is A Precursor To A Known Carcinogen.

158. Dimethyl diazene ("DD"), also known as azomethane, is "associated with the production process of the [PE-PUR] foam."[67] Philips has admitted that DD is emitted from PE-PUR foam under normal conditions and possibly also as the result of degradation.[68]

159. IARC has not yet evaluated the potential carcinogenicity of DD to humans, as there is scant data concerning the effects of DD on humans and animals. However, DD is a member of a family of carcinogenic substances: 1,2-dimethylhydrazine (a Group 2A probable human carcinogen that exhibits hepatotoxic effects along with injuries to other organs in animal experiments[69]) dehydrogenates into DD, which then oxidizes into azoxymethane (a known

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[64] *See Ethylene Glycol: Systemic Agent*, NIOSH, *available at* https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750031.html#:~:text=Agent%20Characteristics&text=DESCRIPTION%3A%20Ethylene%20glycol%20is%20a,also%20be%20a%20pharmaceutical%20vehicle. (last accessed Aug. 15, 2022).

[65] *Id.*

[66] *See*, *e.g.*, C.J. Hardy, *et al.*, *Twenty-eight-day repeated-dose inhalation exposure of rats to diethylene glycol monoethyl ether*, Fundam. Appl. Toxicol. 38(2):143-7 (Aug. 1997).

[67] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf. (finding that during "testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)").

[68] *Id.*

[69] G. Choudary, *Toxicological Profile for Hydrazines*, Agency for Toxic Substances and Disease Registry (1997); R.B. Wilson, *Species variation in response to dimethylhydrazine, Toxicology and Applied Pharmacology*, 38:3 (1976); M.A. Bedell, *et al.*, *Cell Specificity in Hepatocarcinogenesis: Preferential Accumulation of O6 Methylguanine in Target Cell DNA during Continuous Exposure of Rats to 1,2-Dimethylhydrazine*, Cancer Res 42:3079-3083 (1982); W.J. Visek, *et al.*, *Dietary protein and chronic toxicity of 1,2-dimethylhydrazine fed to mice*, Journal of Toxicology and Environmental Health, 32:4, 383-413 (1991).

carcinogen that has not yet been classified by the EPA or IARC). Azoxymethane further oxidizes into methylazoxymethanol, a Group 2B possible human carcinogen.[70] Both methylazoxymethanol and 1,2-dimethylhydrazine have been found to metabolize into formaldehyde, a Group 1 known carcinogen.[71] Thus, an individual regularly exposed to DD may also have been exposed to 1,2-dimethylhydrazine, azoxymethane, methylazoxymethanol, and/or formaldehyde—each of which is recognized as a known or probable carcinogen—as these compounds are oxidized and metabolized.

160. DD is clearly linked to colorectal cancer in mice. Azoxymethane, the product of oxidized DD, is used to induce colorectal cancer in animals and has been shown to cause hepatic lesions, intestinal tumors, and renal tumors.[72] Oxidized azoxymethane produces methylazoxymethanol, which is known to cause DNA damage and has been associated with amyotropic lateral sclerosis, parkinsonism, dementia, colon cancer, liver cancer, and prostate cancer.[73] Exposure to DD—as the precursor to these carcinogenic compounds—means exposure to these other compounds and the health risks they pose.

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[70] E. Fiala, *Investigations into the metabolism and mode of action of the colon carcinogen 1, 2-dimethylhydrazine*, Cancer, 36:2407-12 (Dec. 1975); S. Wolter, N. Frank, *Metabolism of 1,2-dimethylhydrazine in isolated perfused rat liver*, Chemico-Biological Interactions, 42:3, 335-344 (1982); IARC Monograph – 71-42, IARC (1987); IARC Monograph Supplement 7, IARC (1987); H. Druckrey, *Production of colonic carcinomas by 1,2-dialkylhydrazines and azoxyalkanes*, Carcinoma of the Colon and Antecedent Epithelium 267-279 (1970).

[71] P. Harbach, *et al*., *Effects of selenium on 1,2-dimethylshydrazine metabolism and DNA alkylation* (1981); S.N. Newaz, *et al*., *Metabolism of the Carcinogen 1,2Dimethylhydrazine by Isolated Human Colon Microsomes and Human Colon Tumor Cells in Culture* (1983); J. Erikson, *et al*., *Oxidative Metabolism of Some Hydrazine Derivatives by Rat Liver and Lung Tissue Fractions* (1986).

[72] M. Kobaek-Larsen, *et al*., *Secondary effects induced by the colon carcinogen azoxymethane in BDIX rats*, APMIS 112(6):319-29 (2004 Jun.).

[73] P. Spencer, *et al*., *Unraveling 50-Year-Old Clues Linking Neurodegeneration and Cancer to Cycad Toxins: Are microRNAs Common Mediators?*, Frontiers in Genetics 3 (2012).

6. Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) Is A Toxic Compound.

161. Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl) ("DTBSBP") is "associated with the production process of the foam." [74] According to Philips, DTBSBP is emitted from PE-PUR foam under normal conditions and possibly also as the result of degradation.[75]

162. In 2010, the Canadian government determined that DTBSBP was a Schedule 1 toxic substance under the Canadian Environmental Protection Act "based on available information regarding possible persistence, accumulation in organisms and potential to cause harm to organisms."[76] These findings prompted Canadian regulators to propose "virtual elimination" of DTBSBP.[77]

E. PHILIPS KNEW OF THE DANGERS OF PE-PUR FOAM FOR MANY YEARS PRIOR TO THE RECALL.

163. At the time it installed PE-PUR foam into the Recalled Devices, Philips was required to test the devices in accordance with ISO 18562-2:2017 and ISO 18562-3:2017.

164. At that time, Philips should have known the PE-PUR foam posed a safety risk to users.

165. The FDA concluded after an investigation of Philips' Recalled Devices that beginning in at least 2008, and over time, Philips received hundreds of thousands of customer

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[74] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf (finding that during "testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)").

[75] *Id.*

[76] *Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)- (DTBSBP)*, Government of Canada, Canada.ca, *available at* https://www.canada.ca/en/health-canada/services/chemical-substances/challenge/batch-8/1-methylpropyl.html. (last accessed Aug. 15, 2022).

[77] *Id.*

complaints regarding foam degradation in the Recalled Devices and, years later, received data from a variety of sources confirming foam degradation.

166. The FDA's findings were based, in part, on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021 and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's findings in a 28-page FDA-483 Report issued on November 9, 2021.[78] The FDA delivered the 483 Report to Rodney Mell, Head of Quality and Regulatory at Philips Respironics, on or around November 9, 2021.[79]

167. A 483 Report "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."[80] These observations are made in a 483 Report "when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been . . . or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."[81]

168. In connection with the FDA's investigation for its 483 Report, the FDA learned that Philips received hundreds of thousands of complaints from customers about degradation of the foam in its Recalled Devices beginning at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices**. Additionally, your firm

[78] FDA 483 Report, *available at*: https://www.fda.gov/media/154244/download.

[79] *Id.* at 1, 28.

[80] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last accessed Aug. 15, 2022).

[81] *Id.*

> performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to 2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021**.[82]

169. Yet, "[n]o formal investigation, risk analysis, or CAPA were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017 . . . ."[83]

170. A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct a quality problem after one is detected. *See* 21 C.F.R. § 820.100. A CAPA is designed "to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence."[84]

171. The FDA also found that Philips "was made aware of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015 . . . ."[85]

172. In fact, an adverse event report from the FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Philips knew that a patient discovered "black dust" on her nose when she awoke after using a Philips RemStar CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness."[86]

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[82] 483 Report at 12 (emphasis added).

[83] *Id.* at 16.

[84] https://www.fda.gov/corrective-and-preventive-actions-capa (last accessed Aug. 15, 2022).

[85] *Id*. at 18.

[86] MAUDE Adverse Event Report: RESPIRONICS, INC. REMSTAR PRO INTERNATIONAL, http://www.fdable.com/advanced_maude_query/324fd08a137ce36c2d5faf453ee26f2f (last visited Aug. 15, 2022).

173. Philips investigated this report and confirmed that the device contained "evidence of an unk[nown] black substance in the air path and on internal components . . . present throughout both the intake and exhaust portions of the air path . . . ."[87]

174. The FDA found that Philips' analysis of consumer complaints was itself defective in that it "was not adequately performed to identify or detect quality problems."[88] The FDA concluded that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions."[89] In light of this, the FDA concluded that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.[90]

175. The FDA has concluded that:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.[91]

176. The FDA 483 Report notes that "an incorrect and non-specified polyester polyurethane, raw foam product, sourced from your [Philips'] raw foam supplier resulted in non-conforming Trilogy Evo ventilatory finished devices being approved, released, and distributed

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[87] *Id*.

[88] 483 Report at 16.

[89] *Id.* at 13.

[90] *Id.* at 3.

[91] https://www.fda.gov/media/158129/download (last accessed Aug. 15, 2022) ("518(b) Notice"), at 6.

which further resulted in the ongoing correction and removal."[92] The correction and removal "were established as part of [Philips'] response to failed VOC and ISO 18562 testing of related Trilogy EVO ventilatory medical devices, which resulted from the presence of the non-specified polyester polyurethane foam component, incorrectly supplied by [Philips'] raw foam supplier."[93]

177. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the FDCA, 21 U.S.C. § 360h(b) (the "518(b) Notice").[94] The 518(b) Notice stated that the FDA's "Center for Devices and Radiological Health (CDRH) is proposing that an order should be issued pursuant to section 518(b)" of the FDCA "to require Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated."[95] This notice was directed to Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, for Philips Respironics, Inc.

178. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."[96]

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[92] 483 Report at 25.

[93] *Id.*

[94] 518(b) Notice, available at https://www.fda.gov/media/158129/download.

[95] 518(b) Notice at 1.

[96] *Id.* at 2.

179. The FDA concluded that "patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices[.]"[97]

180. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR foam."[98]

1. In 2015, Philips Communicated With Its Foam Suppliers About The Problem Of PE-PUR Foam Degradation.

181. The PE-PUR foam that Philips used in its Recalled Devices was manufactured by William T. Burnett & Co. ("Burnett"), a bulk foam manufacturer. Burnett produces foam in sheets that are between approximately four feet to more than six feet wide and may be as long as one hundred or two hundred feet.

182. Burnett sells its bulk foam to intermediaries, including PolyTech and The SoundCoat Company ("SoundCoat"). PolyTech and SoundCoat then sell the foam to Philips, either directly or through another intermediary, such as Paramount Die Corporation, which may modify the foam.

183. According to the FDA, "email correspondence between [Philips] and its raw foam supplier [PolyTech] beginning 10/30/2015 and forward, document that [Philips] was made aware of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015, which was later confirmed by [Philips'] foam supplier on 08/05/2016, via email."[99]

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[97] *Id.*

[98] *Id.* at 6.

[99] 483 Report at 18.

184. On August 5, 2016, Bob Marsh, a PolyTech employee, wrote to Lee Lawler,[100] an employee of Burnett, referencing a concern expressed by one of its customers, Philips, in the Fall of 2015 regarding foam degradation in its medical devices.[101] Mr. Marsh stated: "They [Philips] are asking again, and wondered if we could give them any estimate on lifespan of the foam when exposed to 40 C and high humidity."[102] Mr. Lawler responded that, under those conditions, he "would not be surprised if ester foam . . . would exhibit signs of hydrolysis in as short a time as a year."[103] He added: "that is not a good environment for polyester foam. Polyether foam could last years in that environment."[104] Presumably referring to Philips, Mr. Marsh responded that he would "let them know they'd be better off with the ether."[105]

185. Knowing about these issues with the PE-PUR foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material.'"[106] Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.[107]

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[100] The Affidavit of Lee Lawler, Technical and R&D Manager at Burnett, is filed in MDL 3014, Case 2:21-mc-01230-JFC, at Doc. 589-7 and attached hereto, without exhibits, as Exhibit "C" ("Lawler Aff.").

[101] *See* Email exchange between Bob Marsh at PolyTech and Lee Lawler at Burnett (Lawler Aff. Exh. E) (Exh. "D" hereto), at WTB 000056.

[102] *Id.*

[103] *Id.*

[104] *Id.*

[105] *Id.*

[106] 518(b) Notice at 7.

[107] *Id.*

186. According to the FDA, "no further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by Philips at that time . . . and no preventative maintenance procedures were implemented[,]" other than a limited "preventative maintenance procedure" instituted by a Philips "entity owned by the parent company of Philips Respironics . . . to replace the air intake assembly of Trilogy ventilator products, due to complaints that had been received regarding degradation of the PE-PUR foam contained in the products."[108] And even then, "Philips did not verify the effectiveness of this measure."[109]

187. As Philips continued to ask its supplier about the properties of the PE-PUR foam and encountered more warning signs, it continued to put that foam in medical devices that millions of its customers were breathing through daily.

188. Testing conducted for Philips in 2016 confirmed that Mr. Lawler from Burnett was correct. According to the FDA, this testing "determined that the PE-PUR foam was susceptible to degradation, resulting in the conclusion at that time that 'polyester urethanes show bad resistance against high humidity in combination with high temperature.'"[110] Additional testing "determined that, compared to PE-PUR foam, another type of foam, polyether urethane, 'show[s] a far better resistance against high humidity at high temperature.'"[111]

189. The 483 Report identified "at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with

[108] *Id.* at 6-7.

[109] *Id.* at 8.

[110] *Id.* at 7-8.

[111] *Id.* at 8.

various Sleep and Respiratory care devices."[112] It listed the specific analyses and tests, including one which concluded that "contrary to polyester urethane foams, [redacted] foams shows a far better resistance against high humidity at high temperature."[113]

190. Philips received at least 110 complaints confirmed to be related to foam degradation between 2014 and 2017.[114] Approximately 80 of these complaints concerned CPAP and BiPAP devices.[115]

191. Nonetheless, Philips continued manufacturing and selling the now Recalled Devices containing PE-PUR foam and failed to warn prescribing physicians, durable medical equipment companies and the patient consumers of this problem.

2. Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018 That Confirmed PE-PUR Foam Is Prone To Degradation.

192. In April 2018, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA INV 0988, "to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken."[116] Philips reported that "[u]nits were returned from the field where the Trilogy Removable Air Path Foam [redacted] and the foam in the Inlet Air Path Assembly [redacted] was degrading, and getting into the motor/air path, causing at least 1 Trilogy unit to fail."[117]

193. On April 20, 2018, Vincent Testa, a Project Mechanical Engineer at Philips, emailed Bonnie Peterson, a Project Manager at PolyTech. Mr. Testa stated, "We use the PAFS

[112] 483 Report at 3.

[113] *Id.* at 4.

[114] 518(b) Notice at 7.

[115] *Id.* at 8.

[116] *Id.*

[117] 483 Report at 14.

foam in the air path of our Trilogy family of ventilators as a means for noise reduction . . . ."[118] PAFS foam is PolyTech's open cell, flexible acoustical grade PE-PUR foam.[119] Mr. Testa at Philips continued: "Recently weve [*sic*] received a few complaints from our customers that the foam is disintegrating . . . . The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users."[120] Mr. Testa asked, "what could cause this material to break down."[121]

194. On April 23, 2018, Mr. Marsh from PolyTech forwarded Philips' April 20, 2018 email to Mr. Lawler from Burnett, reporting that "[t]he customer [Philips] is finding degradation of the ester foam and the urethane film in their device, such that particles are breaking off and flowing in the airstream."[122]

195. On May 2, 2018, Mr. Marsh added in an email to Mr. Lawler that "Philips gave us another bit of information. They tested ether vs ester in high heat and humidity and found ether to be the better performer. It validated what we (you) had conveyed."[123] Mr. Marsh asked whether exposure to oxygen, higher temperature, and higher humidity could accelerate deterioration of PE-PUR foam.[124]

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[118] *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (attached hereto as Exhibit "E"), at WTB 000070.

[119] https://www.polytechinc.com/products/acoustic-foam (last accessed Aug. 15, 2022).

[120] *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000070.

[121] *Id.*

[122] *See* Email from Bob Marsh to Lee Lawler dated 4/23/2018 (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000069-000070.

[123] *See* Email from Bob Marsh to Lee Lawler dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000069.

[124] *Id.*

196. Mr. Lawler responded that he did "not believe that exposure to oxygen will cause any significant damage to polyurethane foam unless elevated temperature and/or humidity is also present."[125]

197. On May 3, 2018, Mr. Testa from Philips admitted in a follow-up email to Mr. Marsh from PolyTech, that:

> We [Philips] are evaluating our options regarding the foam. We could switch to the PAF [ether-based foam], or we could indicate a preventative maintenance cycle in which they would replace the PAFS [ester-based] foam pieces. . . . The environmental conditions for our device are a maximum of 40C and 95% R.H. Note the difference in temperature.[126]

198. Mr. Testa at Philips asked Mr. Marsh from PolyTech the following:

1. Please ask your foam supplier to calculate the service life based on this higher temperature (40C vs. 27C).
    a. It would also be useful if they could provide a graph depicting failure over time. For example, if tensile strength reduced over time, they would plot strength vs. time.
2. At the end of the service life, what is the failure mode of this material?[127]

199. Mr. Marsh again forwarded these questions to Mr. Lawler at Burnett, who responded:

> I am unable to answer Question Number 1. We would not recommend using **polyester** foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. **Polyether** foam lifetime would not be expected to reduce significantly at the stated conditions. Use with pure oxygen could shorten the lifetime some by promoting more rapid oxidation. I do not know the extent of the reduction, but do not expect it to be overly significant.

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[125] *See* Email from Lee Lawler to Bob Marsh dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000069.

[126] *See* Email from Vincent Testa to Bob Marsh dated 5/3/2018 (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000068-69).

[127] *Id*.

> Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95% R.H.[128]

200. Mr. Lawler from Burnett added: "Is it one of our data sheets that states foam lifetime being 10 years at 95% R.H? I do not think I have seen a sheet with that statement."[129] Mr. Marsh at PolyTech responded that he would pass along the information to Philips and that "[w]e have no idea where that statement came from. It has been on our data sheets for probably 20 years. We are removing it."[130]

201. On May 23, 2018, Mr. Marsh from PolyTech forwarded to Mr. Lawler from Burnett another question from Mr. Testa at Philips about the degradation of the foam it was using in its Recalled Devices.[131] Mr. Testa explained that Philips had "sent samples to a local lab for analysis."[132] The local lab concluded that the degradation was a result of cleavage of the bonds in the base polymer, and Mr. Testa stated that "[f]urther investigation concluded that prolonged exposure to high humidity causes the foam to degrade."[133] Mr. Testa noted that "[a]s the foam

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[128] *See* Email from Lee Lawler to Bob Marsh dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000067-68 (emphasis in original).

[129] *Id.* at WTB 000068.

[130] *See* Email from Bob Marsh at PolyTech to Lee Lawler at Burnett dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000067. Notably, PolyTech still advertises on its website that PE-PUR foam is resistant to heat and humidity. *See* https://www.polytechinc.com/products/polymer-acoustic-foam (last accessed Aug. 15, 2022) ("Ester foams have superior physical properties and offer excellent resistance to heat, moisture, and chemicals.").

[131] *See* Email from Bob Marsh to Lee Lawler dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000066-67.

[132] *Id.* at WTB 000066.

[133] *Id.* at WTB 000067.

degrades it breaks down into small particulate" and asked whether the foam "maintain[s] its UL 94 Flame Resistance rating if it is broken down into particulate?"[134]

202. Mr. Lawler replied: "I am sure the degraded foam will not perform well in UL94 testing, though I cannot imagine how one would actually perform the test on such degraded material."[135]

203. On June 7, 2018, Mr. Testa at Philips again emailed Mr. Marsh at PolyTech:

> As we continue our investigation of the deterioration of the PAFS foam, a few questions has [*sic*] been posed regarding the material. Can you please reach out to your foam supplier regarding the following.
>
> 1. What is the actual composition of the polyurethane-ester foam PAFS-038? (CAS #s/percentages/weight percent/reactive groups etc. any chemistry is very appreciated)
> 2. What kind of diisocynate is used in the polyurethane foam synthesis process and how much?
> 3. Is diethylene glycol or another polyol utilized in the foam synthesis process?
> 4. Have you tested to see if all diisocyanate groups are reacted in your foam or are there unreacted groups even after manufacturing?[136]

204. Mr. Marsh (PolyTech) forwarded the questions to Mr. Lawler (Burnett), who asked why Mr. Testa (Philips) needed this information. Mr. Marsh did not provide a definitive answer but said, "What Vince [Testa] told us is that they are investigating alternatives to polyurethane

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[134] *Id.*

[135] *See* Email from Lee Lawler to Bob Marsh dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit "E" hereto), at WTB 000066.

[136] *See* Email from Vincent Testa to Bob Marsh dated 6/7/2018 (Lawler Aff. Exh. I) (attached hereto as Exhibit "F"), at WTB 000076-77.

foam (ester and ether)."[137] Mr. Lawler ultimately did not answer Mr. Testa's questions because they touched on Burnett's confidential, proprietary information.

205. On June 20, 2018, Philips closed CAPA INV 0988.[138] According to the FDA, Philips implemented "a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure."[139] Yet, "after CAPA INV 0988, Philips modified its CAPA procedures to include 'requirements to help ensure that CAPAs are fully complete [and] appropriately scoped,' and that 'processing the issue [that was the subject of CAPA INV 0988] through the current CAPA program would have result[ed] in an appropriate horizontal assessment.'"[140]

206. The FDA pointed out that Philips' informal CAPA INV[141] related to these Trilogy devices did "not include, investigate, or examine all of [Philip's] CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane [PE-PUR] foam, which is susceptible to degradation."[142] But Philips had acknowledged to the FDA that it had "received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices**, from 2014 to 2017."[143]

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[137] *See* Email from Bob Marsh to Lee Lawler dated 6/14/2018 (Lawler Aff. Exh. I) (Exhibit "F" hereto), at WTB 000075.

[138] 483 Report at 15.

[139] 518(b) Notice at 8.

[140] *Id.*

[141] The 483 Report explained that Philips's practice at the time was to first open CAPA requests—called "CAPA INVs"—as a precursor to a formal CAPA, but this could only occur if approved by a "CAPA Review Board" or delegate. *See* 483 Report at 14-15.

[142] *Id.* at 15.

[143] *Id.* at 16 (emphasis added).

207. The FDA concluded that Philips had not "adequately established" a process for initiating CAPA procedures.[144] Specifically, the FDA faulted Philips for not initiating a "formal" CAPA after receiving "various complaints alleging foam degradation in Trilogy ventilator devices" and then closing its informal investigation just two months later without "verify[ing] the effectiveness" of the limited "preventative maintenance procedure for Trilogy devices."[145]

208. Philips continued to receive more information suggesting that the PE-PUR foam was prone to degradation. According to the FDA, "[a] follow-up email amongst [Philips'] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints . . . ."[146]

209. Further, "[o]n December 12, 2018, several months after CAPA INV 0988 was closed, a report from additional testing conducted for Philips found that '[p]olyester polyurethane foam showed clear disintegration after 2 weeks."[147]

210. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR foam.

211. Philips failed to apprise the FDA of the facts and problems it learned from its foam suppliers about premature foam degradation risks.

212. Philips failed to apprise the FDA of consumer, medical provider and durable medical equipment company reports of the presence of foam particles and other device failures.

213.

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[144] *Id.* at 14.

[145] 518(b) Notice at 8.

[146] 483 Report at 18.

[147] 518(b) Notice at 8.

3. Philips Finally Opened A Formal CAPA In 2019 – But Did Not Initiate A Recall For Two More Years.

214. In April 2019, Philips received two complaints that "sound abatement foam 'is degrading and entering the air path[.]'"[148]

215. In response, in June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MDR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with CAPA INV 0988.[149]

216. Philips continued to test the PE-PUR foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern…."[150]

217. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in various CPAP and ventilator products"[151] – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

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[148] *Id.*

[149] *Id*. at 8-9.

[150] 483 Report at 7; *see also id*. ("Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.").

[151] *Id.* at 8.

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**[152]

218. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR foam "presents a significant biological risk to patients," and admitted that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."[153]

219. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity" and reiterated that "the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."[154]

220. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything to rectify or mitigate the hazards:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.
>
> Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings,

[152] *Id.* at 7-8 (emphasis added).

[153] *Id.* at 8.

[154] 518(b) Notice at 10.

since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.[155]

F. PHILIPS CONSISTENTLY MARKETED ITS BREATHING MACHINES AS SAFE AND EFFECTIVE EVEN WHEN IT KNEW OF THE PROBLEMS WITH PE-PUR FOAM DEGRADATION AND ASSOCIATED HEALTH RISKS.

1. Philips Never Hinted at the Dangerous Condition of the Recalled Devices.

221. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in its recalled CPAP, BiPAP, and ventilator devices. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets."[156] Its branding promises consumers that they will "[b]reath easier, sleep more naturally[.]"[157] Philips further assures consumers that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing enhanced patient comfort," among other things.[158] And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatment for sleep disorders.[159]

222. Philips boasts that it has the "most prescribed CPAP systems by U.S. sleep physicians."[160]

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[155] 483 Report at 24.

[156] http://www.respironics.com/product_library (last accessed Aug. 15, 2022).

[157] *Id*.

[158] *Id.*

[159] https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (last accessed Aug. 15, 2022).

[160] *Id.*

2. Philips Knew Some of its Customers Were Using the SoClean Zone Cleaning Technology with its Devices and Assented to Such Use.

223. Philips was fully cognizant that many users were utilizing the So-Clean Ozone product in conjunction with its device.

224. For example, on March 6, 2020, in a letter responding to a customer's request for written guidance, Philips Respironics said using SoClean on its DreamStation will not automatically void the warranty, but the company "reserves the right to void a warranty if it is determined that the use of SoClean caused a defect for which a device otherwise under warranty was returned." The company said in a statement to HME News that it "does not formally validate the use of SoClean with the DreamStation, but as of Jan. 6, Philips has not denied a warranty claim associated with the use of SoClean with a DreamStation." Philips told HME News it wrote the letter "to limit confusion and misinformation." The article in HME News further quoted Philips stating that "Philips is in communication with SoClean to further analyze the potential compatibility of the SoClean with DreamStation therapy devices, and will provide further information as it becomes available," the company told HME News.[161]

225. By virtue of that communication to a trade journal, Philips not only acknowledged its awareness of the use of the product, but also acknowledged it received warranty complaints amongst users of the DreamStation who also used SoClean, and honored the warranties and communicated with SoClean.

226. Additional evidence that Philips was aware that SoClean was selling a product specifically designed to be used in conjunction with the DreamStation is the website of CPAPDIRECT.COM, a major internet provider of CPAP machines and related paraphernalia

[161] *Business News For Home Medical Equipment Providers*, March 6, 2020 at https://www.hmenews.com/article/cpap-manufacturers-address-certain-cleaning-devices (last accessed August 22, 2022).

which advertised an express adapter kit for So Clean and Dream Station products.[162] Similarly numerous other internet and durable medical equipment companies and retail suppliers of Philips CPAP devices also sold SoClean to be used in conjunction with the Devices, and Philips was expressly and impliedly was aware of this combined use.

227. Given that Philips was on notice since at least 2008 of a foam degradation concern, and was also aware of the combined use of its Devices with SoClean, to the extent there is any validity to Philips recent claims attributing foam degradation to SoClean ozone treatment, Philips should have and could have made the same attributions and affirmatively stepped up to expressly warn medical providers, Durable Medical Equipment companies and patients against the combined use of the products in allegedly contributing to premature foam degradation.

228. Instead, recognizing that SoClean consumers seemingly liked having this additional cleaning modality, Philips declined to dissuade patients and customers from the combined use due to a concern that they would lose business to alternative CPAP manufacturers who also tacitly or expressly condoned such joint use.

3. Philips Sold Its Humidifier Accessory Allowing Warm Storage Conditions and Contributing to Humidity of the Foam.

229. Philips sold humidifiers to accompany its CPAP devices, especially the DreamStation, stating in the humidifier's User Manual under the heading "Intended Use": "The DreamStation Heated Humidifier is an accessory for the Philips Respironics DreamStation therapy devices to provide moisture to the patient circuit."[163]

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[162] https://www.cpapdirect.com/cleaning/soclean-respironics-system-one-and-dreamstation-adapter (last accessed August 22, 2022).

[163] https://www.documents.philips.com/doclib/enc/11410694/DreamStation_Humidifier_User_Manual.pdf, at 1 (last accessed August 22, 2022).

230. The humidifier manual quoted above had, under the heading "DreamStation Heated Humidifier Specifications" had environmental specifications that included an "Operating Temperature: 5° to 35° C (41° to 95° F")" as well as "Storage Temperature: -20° to 60° C (-4° to 140° F)" and "Relative Humidity (operating & storage): 15 to 95% (non-condensing)."[164]

231. Philips provided the humidifier option explaining in the DreamStation User Manual that "[y]ou can use the heated humidifier and the heated tube with your device. They are available from your home care provider. A humidifier may reduce nasal dryness and irritation by adding moisture to the airflow."[165]

232. Philips not only knew but recommended the use of the humidifier, and also advised that the device could be stored in a room as warm as 140° F despite their knowledge that warm, hot and humid conditions contributed to rapid degradation of its sound insulating foam.

G. PHILIPS FINALLY RECALLED ITS DEFECTIVE DEVICES CONTAINING HAZARDOUS PE-PUR FOAM, BUT ONLY AFTER LAUNCHING ITS NEWEST DEVICE WITHOUT PE-PUR FOAM.

1. Prior to the Recall, In April And May 2021, Philips Launched The DreamStation 2 (Which Does Not Contain PE-PUR Foam).

233. Two months prior to the Recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR foam.

234. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips announced that its previous generation of DreamStation products and other Recalled Devices posed serious health risks to users. In the same release, Philips tried to convince consumers to purchase and use its new DreamStation 2 device:

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[164] *Id.* at 12.

[165] *See, e.g.*, Exh. B-1 (DreamStation User Manual), at 22.

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone,* and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. ***Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected***. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.[166]

2. Testing Continued To Confirm The Recalled Devices Were Defective and the FDA Received Additional MDRs.

235. Even as it launched the DreamStation 2 device and announced publicly that its previous generation DreamStation products posed serious health risks to users, Philips continued to conduct tests that confirmed some of its breathing products were defective.

236. For example, on May 17, 2021, Ken Cole from RJ Lee, an industrial forensics analytical laboratory and scientific consulting firm, produced a presentation analyzing the foam in Philips' Trilogy EVO devices. The presentation states that the investigation was "prompted by staff observation of color variance across both current production and previous builds."[167]

237. The analysis involved six samples of foam, two from units built in 2018 and four taken from Philips' current production stock in May 2021.[168] Some of the samples from 2021 showed "differing cell structure" which is an "[i]ndication of poor process control."[169] The 2021

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[166] https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last accessed Aug. 15, 2022) (emphasis added).

[167] *See* RJ Lee Analysis Review of Trilogy EVO Foam (Lawler Aff. Exh. A) (attached hereto as Exhibit "G"), at (WTB 000003).

[168] *Id.* at WTB 000006.

[169] *Id.* at WTB 000008.

foam had "significant contaminants."[170] The foam was supposed to be ether-based,[171] but testing revealed indications that some of the foam was actually ester-based.[172]

238. In addition, MDRs associated with the PE-PUR foam breakdown increased significantly.[173] From 2011 to April 2021 when Philips first notified the FDA of their intention to conduct a field action due to concerns pertaining to foam degradation (breakdown) in certain ventilators, BiPAP machines, and CPAP machines, Philips submitted only 30 MDRs that they identified as associated with the PE-PUR foam breakdown and there were no reports of patient injury or death among those 30 MDRs.[174] Eight of those reports were from the United States.

239. After Philips notified the FDA of its intention to conduct a field action in April 2021 through July 31, 2022, the amount of MDRs the FDA received increased significantly as did the "reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown."[175] Specifically, the FDA reported:

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[170] *Id.* at WTB 000009; *see also* WTB 000010 ("Indication of poor process control and/or contamination.").

[171] *Id.* at WTB 000002.

[172] *Id.* at WTB 000013.

[173] As stated above, manufacturers, such as Philips, are required to submit medical device reports (MDRs) when information reasonably suggests that their device may have caused or contributed to a death or serious injury, or has malfunctioned, and that device or a similar device they manufacture would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Health professionals, consumers, and patients may voluntarily submit reports of device adverse events and malfunctions to the FDA. *See, e.g.*, 21 C.F.R. § 803.20.

[174] The FDA's latest information about medical device reports (MDRs) associated with the Recalled Devices on August 16, 2022 is available here: https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due?utm_medium=email&utm_source=govdelivery#mdr (last accessed Aug. 17, 2022) ("FDA MDR Update").

[175] *Id*. (stating "The MDRs received included both mandatory reports from Philips and voluntary reports from health professionals, consumers, and patients.").

- From April 2021 through April 30, 2022, the FDA received more than 21,000 MDRs, including 124 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.

- From May 1, 2022, through July 31, 2022, the FDA received more than 48,000 MDRs, including 44 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.

240. The FDA continued: "A wide range of injuries have been reported in these MDRs, including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain."[176]

3. Finally, In June 2021, Philips Recalled Its Defective Devices.

241. Finally, on June 14, 2021, Philips issued a recall notice directed to its customers in the United States, stating:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device 's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.
>
> Therefore, Philips has decided to voluntarily issue a recall notification* to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.[177]

242. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family."[178] Philips elaborated:

> Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification advises patients and customers to take the following actions:

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[176] *Id.*

[177] Recall Notices (Exhibit "A" hereto).

[178] *Id.*

> For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.
>
> For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.
>
> **Possible health risks**
>
> The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.[179]

243. Corroborating the dangerous nature of the Recalled Devices, on July 22, 2021, the FDA upgraded Philips' recall of the Recalled Devices to its most serious classification, Class I, which according to the FDA means: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."[180]

[179] *Id.*

[180] https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions (last accessed Aug. 15, 2022).

244. Philips' Recall announcement instructed users to not use the Recalled Devices because of the health risks. This confirmed the true nature of the products, which at all times were adulterated and worthless.

245. Philips took similar action with respect to its defective CPAP, BiPAP, and ventilator devices across the globe.

246. Also, on June 14, 2021, Philips' main competitor, ResMed, issued "[a] message from ResMed's CEO" to the public regarding the Philips Recall. In this notice, ResMed CEO, Mick Farrell, stated that "ResMed devices are safe to use and are not subject to Philips' recall. ResMed devices use a different material than what Philips uses in their recalled machines."[181]

247. ResMed devices and ventilators use polyether polyurethane or silicone-based foam, not PE-PUR foam, for sound abatement purposes.[182]

H. THE MEASURES TAKEN BY PHILIPS TO RECALL THE DEFECTIVE DEVICES WERE INEFFECTIVE.

248. Philips' CEO, Frans van Houten, stated in the Recall announcement: "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety."[183]

249. But Philips' "recall" was a recall in name only. It did not effectively provide patients with notice of the risks of the Recalled Devices nor did it provide them with new Philips CPAP, BiPAP, or ventilator devices.

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[181] https://www.resmed.com/en-us/healthcare-professional/other-manufacturer-recall-2021/ (last accessed Aug. 15, 2022).

[182] https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Aug. 15, 2022).

[183] https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (last accessed Aug. 15, 2022).

1. Many Patients, Providers, And Others Were Not Notified About The Recall.

250. On March 10, 2022, the FDA issued a Notification Order under § 518(a) of the FDCA.[184] The Notification Order stated that the "FDA has received a number of calls from patients and consumers who contacted FDA to report problems and/or concerns regarding the Recalled Products, but were unaware of the recall and had not been informed of the health risks presented by the Recalled Products."[185]

251. The FDA estimated that, after nine months of the Recall, "approximately 50% of patients and consumers who have purchased or received the Recalled Products (excluding ventilators) within the last five years (the service life of the devices) have registered with Philips to obtain a replacement device."[186] But it was "unclear whether the remaining patients and consumers have not registered because they are unaware of the need to register, or because they do not want or need a replacement device from Philips."[187]

252. The FDA surveyed 182 consignees to determine whether they had been notified of the Recall and found 28 "who had reported to FDA that they were not aware of the recall."[188] The FDA reported its results to Philips on September 8, 2021 and October 29, 2021, but Philips did not promptly respond. Almost a month later, on November 22, 2021, Philips stated that it had notified 23 of the 28 consignees of the Recall, but Philips did not "indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA

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[184] See 518(a) Notification Order, available at: https://www.fda.gov/media/156811/download (last accessed Aug. 15, 2022).

[185] 518(a) Notification Order at 2.

[186] *Id.*

[187] *Id.*

[188] *Id.*

as being unaware of the recall."[189] Moreover, Philips' evidence of notification consisted of delivery confirmation receipts, reflecting that written correspondence was delivered to the consignees. As the FDA explained, "[t]ypically, firms demonstrate the effectiveness of its recall communications through evidence more meaningful than a delivery confirmation receipt, such as a returned response form or a documented telephone conversation."[190]

253. Throughout the Recall, the FDA "on multiple occasions has informed Philips that FDA was concerned that Philips' efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient," and has expressed concern that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products."[191]

254. Noting "Philips' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products," the FDA issued an order under Section 518(a) of the FDCA ordering Philips to give adequate notice.[192] Specifically, the FDA ordered Philips to "notify all health professionals who prescribe or use the Recalled Products, and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products **within the next 45 days**[.]"[193]

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[189] *Id.*

[190] *Id.* at 3.

[191] *Id.*

[192] *Id.* at 4.

[193] *Id.* (emphasis in original).

2. Philips' Repair/Replacement Program Has Been Extremely Slow.

255. Those patients who registered their Recalled Devices with Philips for the Recall did not immediately receive replacement devices and were not told when a replacement device would be provided.

256. As Philips' June 14, 2021 announcement explained:

> **Repair and replacement program**
>
> Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.
>
> As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program, Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.[194]

257. In reality, patients may register their DreamStation Recalled Device with Philips for the Recall, but Philips has not immediately replaced the defective PE-PUR foam in the DreamStation Recalled Devices. Rather, patients have had to wait, sometimes for many months, for Philips to repair or replace their devices, and many patients are still waiting for a replacement device.

258. As of the date of this Complaint—over a year after the Recall was announced—Philips continues to repair or replace defective DreamStation 1 Recalled Devices. In other words, the Recall remains ongoing.

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[194] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam (last accessed Aug. 15, 2022).

259. The replacement program for the Trilogy devices has been even slower. Philips has only just begun the rework of affected Trilogy 100/200 devices and Philips projects that the process will take approximately 12-14 months to complete.[195]

260. There is no repair or replacement program for any of the other Recalled Devices recalled by Philips.

261. Due to the design of the Recalled Devices, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. Also, the FDA warns:

> Do **not** try to remove the foam from your device. Trying to or successfully removing the foam may damage the device or change how the device works. It may also lead to more foam or chemicals entering the air tubing of the device.[196]

262. As a result, the Recall leaves patients without safe, free options. Instead, patients may simply be forced to buy Philips' next-generation product or a competitor's product—at full price, and indeed, thousands of patients have already done so.

263. Thus, Philips intends to, and is, profiting from its "recall" by selling more of its next generation product, the DreamStation 2, whose launch appears intentionally timed to coincide with the "recall."

264. The FDA also believes that the Recall is not proceeding quickly enough. It recently stated:

> Based on the status of Philips' recall as of the date of this letter [May 2, 2022], CDRH believes that, if an order were to be issued to Philips under section 518(b), the plan submitted by Philips in response to that order should provide for significant improvements to Philips' ongoing repair and replacement activities to speed the pace of remediation and address other deficiencies identified by CDRH and

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[195] https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/ventilation-news-and-updates (last accessed Aug. 12, 2022).

[196] https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls (emphasis in original) (last accessed Aug. 15, 2022).

communicated to Philips, to the extent such improvements are achievable by Philips.[197]

I. PLAINTIFFS AND CLASS MEMBERS HAVE SUFFERED PRESENT INJURY IN THAT THEY NEED TO INCUR THE COST OF MEDICALLY NECESSARY DIAGNOSTIC TESTING DUE TO THEIR INCREASED RISK OF DISEASE CAUSED BY EXPOSURE TO PHILIPS' PE-PUR FOAM

265. Plaintiffs and Class members used the Recalled Devices containing PE-PUR foam, and Philips has admitted that PE-PUR foam releases toxic and carcinogenic Foam Toxins. Plaintiffs and Class members have been significantly exposed to the proven hazardous Foam Toxins released by PE-PUR foam in the Recalled Devices. Plaintiffs and Class members have inhaled and/or ingested these Foam Toxins through their respiratory tract and gut, where they were absorbed into tissue and into Plaintiffs' and Class members' bloodstream, producing subcellular or other physiological changes in Plaintiffs and Class members. Plaintiffs and Class members are presently at an increased risk of illness, disease, or disease process, including cancer.

266. Use of the Recalled Devices has resulted in consumers suffering from cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects.

267. It has been widely accepted for decades that certain of the Foam Toxins (specifically formaldehyde, DEG, and DD's precursor and successor compounds) are toxic and/or carcinogenic to humans. For decades, scientific literature and regulatory agencies around the world have made clear that exposure to the Foam Toxins causes various adverse health effects, including cancers, among multiple species of laboratory animals, including hepatic cancer and tumors,

[197] 518(b) Notice at 13.

mammary gland tumors, pancreas tumors, lesions, intestinal tumors, and renal tumors, as well as tumors of the subcutaneous tissue and blood vessels.[198]

268. Philips understood, at all relevant times, that a chemical that causes cancer in animal studies must be presumed to present a risk of cancer to humans, except in extraordinarily limited circumstances; specifically, when (1) the precise mechanism of action that causes tumors is known, and (2) it is also known that the mechanism of action is either not operative or cannot occur in humans. That extraordinary circumstance does not exist here.

269. Studies show that the persistent exposure to the Foam Toxins results in their presence, accumulation, toxic invasion, and/or persistence in the human bloodstream, including the bloodstream of Plaintiffs and Class members; resulting in injurious, physically harmful, unwanted, unconsented-to, and deleterious alterations, changes, and/or other presently-existing physical injuries and/or adverse impacts to the blood and/or bodies of Plaintiffs and Class members, including but not limited to subcellular injuries.

270. Moreover, based on available scientific literature, exposure to the Foam Toxins places Plaintiffs and Class members at risk of developing a number of serious illnesses and diseases, including but not limited to the following: cancer, including cancer as of the head, neck, kidneys, liver, brain, pancreas, blood-forming tissue, respiratory system, gastrointestinal system, reproductive system, and lymphatic system; respiratory diseases such as asthma, chronic bronchitis, chronic obstructive pulmonary disease, constrictive bronchiolitis or obliterative bronchiolitis, emphysema, interstitial lung disease, pleuritis, pulmonary fibrosis, sarcoidosis; and chronic sinusitis, chronic rhinitis, and other forms of chronic inflammation. The Foam Toxins are cytotoxic and genotoxic; as such, exposure causes widespread damage to DNA as well as the

[198] The health effects of the Foam Toxins are discussed at length above.

reproductive system, neurological system, and other critical systems.

271. Philips did not seek or obtain permission or consent from Plaintiffs or Class members before engaging in such acts and/or omissions that caused, allowed, and/or otherwise resulted in the contamination of Plaintiffs' and Class Members' bloodstream and/or bodies with the Foam Toxins.

272. As a proximate result of Philips' tortious conduct, Plaintiffs and Class members have been, and are presently, at an increased risk of illness, disease, or disease processes, including cancer, requiring them to incur, both now and in the future, the cost of medically necessary monitoring, diagnostic testing, clinical examinations, and consultations for the early detection of illness, disease, and disease processes arising from their exposure to the Foam Toxins during use of the Recalled Devices.

273. Plaintiffs and Class members have suffered a present bodily injury including, subcellular injury, proximately caused by Philips' tortious conduct. Plaintiffs have a legally protected interest in not being exposed to harmful particles and toxic chemicals—such as the Foam Toxins—that increased the risk of illness, disease, and disease processes. Plaintiffs and Class members also have a legally protected interest in avoiding the present and ongoing medical need for expensive medical monitoring, diagnostic testing, clinical examinations, and consultations.

274. The exposure to the PE-PUR foam in the Recalled Devices and the Foam Toxins, the consequent subcellular or other physiological changes in Plaintiffs and Class members, and the resulting increased risk of illness, disease, and disease processes, has caused Plaintiffs and Class members a present and ongoing economic injury. This economic injury consists of the need to incur the cost of medically necessary monitoring, diagnostic testing, clinical examinations, and consultations for the early detection of illness, disease, and disease processes arising from Philips'

tortious design, manufacture, marketing, sale of, and post-marketing conduct.

275. Plaintiffs and Class members are reasonably concerned and fearful of the effects from exposure to the Foam Toxins. This includes the synergistic effects of having multiple toxic and carcinogenic materials in their blood at the same time; and what such effects will and/or are reasonably likely or probable to do to them and their children, including the well-founded and reasonable fear of cancer and other serious diseases that have long latency periods after such exposures.

276. Plaintiffs and Class members should not have to wait until actual diseases, death, or other adverse effects manifest from the Foam Toxins in their blood and bodies before receiving appropriate medical care to monitor, test, and diagnose deleterious health conditions. In addition, Plaintiffs and Class members should not have to wait for research into the deleterious health conditions caused by the Foam Toxins to be funded.

277. Plaintiffs and Class members should not have to bear the burden of funding and/or performing such medical monitoring, testing, and/or research, which will likely cost millions of dollars, when Plaintiffs and Class members did not consent or provide any permission to Philips to put the Foam Toxins and VOCs in their blood and/or bodies (nor were they even aware they were being contaminated with such compounds), and Philips has reaped billions of dollars in profits. This is particularly true where Phillips deliberately and knowingly caused Plaintiffs' and Class members' exposure to the Foam Toxins, despite their well-documented health hazards. To be sure, Plaintiffs and Class members were not even aware that they were being contaminated with such compounds as a result of Philip's decade-long concealment of the PE-PUR Foam's deleterious degradants and its abdication of FDA mandated duties to adequately test its medical devices and immediately, accurately, and comprehensively report those results, as well as conduct

appropriate post-market investigations concerning adverse events.

278. Medical monitoring is recognized as beneficial for early detection where there is an increased risk of disease from exposure to hazardous substances.[199] The purpose of medical monitoring in the form of diagnostic testing is early identification of latent or unrecognized illness, disease, or disease process so that early treatment can be given to reduce the impacts of the toxic exposure.[200] Medical monitoring is widely accepted as a prudent response to toxic exposure.[201]

279. Philips' tortious conduct constitutes an invasion of the legally protected interests of Plaintiffs and Class members and has injured Plaintiffs and Class members. Plaintiffs and Class members would not have the present and ongoing need to incur the cost of medically necessary monitoring, diagnostic testing, clinical examinations, and consultations to monitor the presence of illness, disease, or disease processes arising from their exposure to the Foam Toxins, and the consequent subcellular or other physiological changes arising therefrom, but for the past and ongoing exposure they suffered owing to the tortious conduct of Philips.

280. Diagnostic and monitoring procedures exist that make possible the early detection of the toxic and carcinogenic effects of the Foam Toxins. These monitoring procedures will benefit Plaintiffs and Class Members because they will allow for the early detection of latent disease

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[199] ATSDR's Final Criteria for Determining the Appropriateness of a Medical Monitoring Program Under CERCLA, 60 FR 38841, July 28, 1995.

[200] *Id.*

[201] *See* http://www.c-8medicalmonitoringprogram.com/docs/med_panel_education_doc.pdf (last accessed August 10, 2021); Department of Environmental Health, *Fernald Medical Monitoring Program*, UNIVERSITY OF CINCINNATI COLLEGE OF MEDICINE, https://med.uc.edu/eh/research/projects/fcc/fmmp-history (last accessed August 10, 2021); Environmental Health & Safety, *Pesticide Users Medical Monitoring Program*, UNIVERSITY OF FLORIDA (revised Jan. 21, 2014), http://www.ehs.ufl.edu/programs/ih/pesticide/ (last accessed August 10, 2021); World Trade Center Health Program, *About the Program*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/wtc/about.html (last updated Dec. 15, 2017).

associated with exposure to toxic PE-PUR foam. Catching cancer and other potentially serious and chronic health issues early often allows for more treatment options, improves patient prognoses, and generally avoids more invasive, risky, and expensive medical interventions later. Overall outlook depends on early diagnosis; the sooner a person is checked, the better the outcome will be.[202]

281. Such monitoring procedures in the form of periodic consultations, clinical examinations, and diagnostic testing conform to the standard of medical care and are reasonably necessary to ensure that disease processes can be identified early and aggressively treated. Effective medical consultations, clinical examinations and diagnostic tests exist for reliable early detection, and early detection combined with effective treatment will significantly decrease the severity of the illness, disease, disease process, or injury. The present value of the costs of such tests is calculable, and Plaintiffs and Class members will prove such costs at trial.

282. Such monitoring procedures include testing and screening necessary to detect the existence of the illnesses, diseases, and disease processes caused by exposure to the Foam Toxins as described herein, including but not limited to blood and laboratory tests; physical examinations; imaging; colonoscopies, endoscopies, and other similar methods for examination; biopsies; pathologic, histologic, and oncologic evaluations; oncologic, histologic, surgical, and other necessary medical consultations; and medical and surgical procedures necessary for diagnosis and treatment.

283. These monitoring procedures are different from what would normally be recommended in the absence of exposure to the Foam Toxins. The general unexposed population

[202] https://www.cancer.org/content/dam/CRC/PDF/Public/8671.00.pdf (last accessed August 10, 2021).

does not receive these procedures as a routine matter of course because, *e.g.*, these tests are designed to detect the specific diseases known to be associated with exposure to the Foam Toxins

284. Because of the exposure to the Foam Toxins, Plaintiffs and Class members have suffered subcellular injury and require medically necessary monitoring, diagnostic testing, clinical examinations, and consultations to diagnose the warning signs of the illness, diseases, and/or disease processes resulting from exposure to the Foam Toxins. Early detection of illness, diseases and disease processes caused by exposure to the Foam Toxins allows Plaintiffs and Class members more treatment options, reduces their cost of treatment, and increases their chances of an improved outcome. The progression from the subcellular or other latent physiological changes in Plaintiffs and Class members to the outward manifestation of serious disease can be delayed for year. If the illness, disease, or disease process is permitted to develop until it becomes obvious, Plaintiffs and Class members will have lost valuable time and as diseases progress, they will likely suffer more severe or long-term adverse health effects and require more costly medical interventions.

285. Plaintiffs' and Class members' present need to incur the cost of medical monitoring, diagnostic testing, clinical examinations, and consultations is reasonably medically necessary as a direct and proximate result of Philips' conduct that caused Plaintiffs' and Class members' exposure to the Foam Toxins, and the subcellular or other physiological changes that have resulted from the exposure.

286. Accordingly, in this Medical Monitoring Class Complaint, Plaintiffs and Class members seek as damages the costs of such medical monitoring for the early detection of illness, disease, and disease processes to allow for early diagnosis and treatment beneficial to Plaintiffs and Class members, or in the alternative, the award of the reasonable and necessary costs for the establishment of a court-supervised program of medical monitoring and diagnostic testing through

equitable and/or injunctive relief.

287. Plaintiffs and Class members also seek all other available and necessary relief in connection herewith, including the establishment of a panel of doctors and scientists to study the effects of the Foam Toxins on the human body and develop medical monitoring procedures for those individuals exposed to such compounds.

V. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

288. The running of any statute of limitations has been equitably tolled by Philips' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiffs and their physicians the true risks associated with the Recalled Devices.

289. As a result of Philips' actions, Plaintiffs were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to the risks and harms set forth here and that those risks and harms were the direct and proximate result of Philips' acts and omissions.

290. Plaintiffs did not have the technical, scientific or medical knowledge and information sufficient to ascertain the cause of their injury prior to learning of the recall and the basis for the recall.

VI. CLASS ALLEGATIONS

291. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and, under Federal Rules of Civil Procedure 23(a), (b)(2), (b)(3), (g), and (c)(4), as representatives of the classes. Specifically, the Class consists of the following:

> **Nationwide Class**: All persons in the United States who have used a Recalled Device at least 30 times.

292. Alternatively, and in addition, Plaintiffs seek certification on behalf of subclasses defined as more fully set forth below and collectively referred to as the "State Subclasses."

293. Plaintiff Pendleton seeks certification on behalf of a subclass defined as follows ("Arizona Subclass"):

> **Arizona Subclass**: All persons in Arizona who have used a Recalled Device at least 30 times.

294. Plaintiffs Autry and Melcher seek certification on behalf of a subclass defined as follows ("Arkansas Subclass"):

> **Arkansas Subclass**: All persons in Arkansas who have used a Recalled Deviceat least 30 times.

295. Plaintiffs Bailey, DiJohn, and Nielson seek certification on behalf of a subclass defined as follows ("California Subclass"):

> **California Subclass**: All persons in California who have used a Recalled Device at least 30 times.

296. Plaintiffs McDaniel and Wolff seek certification on behalf of a subclass defined as follows ("Colorado Subclass"):

> **Colorado Subclass**: All persons in Colorado who have used a Recalled Device at least 30 times.

297. Plaintiffs Leavenworth and Toscano seek certification on behalf of a subclass defined as follows ("Connecticut Subclass"):

> **Connecticut Subclass**: All persons in Connecticut who have used a Recalled Device at least 30 times.

298. Plaintiff Boyle seeks certification on behalf of a subclass defined as follows ("Delaware Subclass"):

> **Delaware Subclass**: All persons in Delaware who have used a Recalled Device at least 30 times.

299. Plaintiff Ragland seeks certification on behalf of a subclass defined as follows ("District of Columbia Subclass"):

> **District of Columbia Subclass**: All persons in District of Columbia who have used a Recalled Device at least 30 times.

300. Plaintiffs Fields, Morris, and Paris seek certification on behalf of a subclass defined as follows ("Florida Subclass"):

> **Florida Subclass**: All persons in Florida who have used a Recalled Device at least 30 times.

301. Plaintiff McCarty seeks certification on behalf of a subclass defined as follows ("Hawaii Subclass"):

> **Hawaii Subclass**: All persons in Hawaii who have used a Recalled Device at least 30 times.

302. Plaintiff Wheeler and Pendleton seek certification on behalf of a subclass defined as follows ("Idaho Subclass"):

> **Idaho Subclass**: All persons in Idaho who have used a Recalled Device at least 30 times.

303. Plaintiffs Baran, Wilson, and McCarty seek certification on behalf of a subclass defined as follows ("Illinois Subclass"):

> **Illinois Subclass**: All persons in Illinois who have used a Recalled Device at least 30 times.

304. Plaintiff Dusza seeks certification on behalf of a subclass defined as follows ("Indiana Subclass"):

> **Indiana Subclass**: All persons in Indiana who have used a Recalled Device at least 30 times.

305. Plaintiff Abarr seeks certification on behalf of a subclass defined as follows ("Iowa Subclass"):

> **Iowa Subclass**: All persons in Iowa who have used a Recalled Device at least 30 times.

306. Plaintiffs Cathers and Fisher seek certification on behalf of a subclass defined as follows ("Kansas Subclass"):

> **Kansas Subclass**: All persons in Kansas who have used a Recalled Device at least 30 times.

307. Plaintiff Margoles seeks certification on behalf of a subclass defined as follows ("Maine Subclass"):

> **Maine Subclass**: All persons in Maine who have used a Recalled Device at least 30 times.

308. Plaintiffs Cotton and Goodall seek certification on behalf of a subclass defined as follows ("Maryland Subclass"):

> **Maryland Subclass**: All persons in Maryland who have used a Recalled Device at least 30 times.

309. Plaintiff Bellotti seeks certification on behalf of a subclass defined as follows ("Massachusetts Subclass"):

> **Massachusetts Subclass**: All persons in Massachusetts who have used a Recalled Device at least 30 times.

310. Plaintiff Boudreau seeks certification on behalf of a subclass defined as follows ("Minnesota Subclass"):

> **Minnesota Subclass**: All persons in Minnesota who have used a Recalled Device at least 30 times.

311. Plaintiff Young seeks certification on behalf of a subclass defined as follows ("Missouri Subclass"):

> **Missouri Subclass**: All persons in Missouri who have used a Recalled Device at least 30 times.

312. Plaintiff David seeks certification on behalf of a subclass defined as follows

("Montana Subclass"):

> **Montana Subclass**: All persons in Montana who have used a Recalled Device at least 30 times.

313. Plaintiffs Mills and Glaub seek certification on behalf of a subclass defined as follows ("Nebraska Subclass"):

> **Nebraska Subclass**: All persons in Nebraska who have used a Recalled Device at least 30 times.

314. Plaintiff Lemus seeks certification on behalf of a subclass defined as follows ("Nevada Subclass"):

> **Nevada Subclass**: All persons in Nevada who have used a Recalled Device at least 30 times.

315. Plaintiff Malone seeks certification on behalf of a subclass defined as follows ("New Hampshire Subclass"):

> **New Hampshire Subclass**: All persons in New Hampshire who have used a Recalled Device at least 30 times.

316. Plaintiff Taylor seeks certification on behalf of a subclass defined as follows ("New Jersey Subclass"):

> **New Jersey Subclass**: All persons in New Jersey who have used a Recalled Device at least 30 times.

317. Plaintiffs Dennett and Rodgers seek certification on behalf of a subclass defined as follows ("New Mexico Subclass"):

> **New Mexico Subclass**: All persons in New Mexico who have used a Recalled Device at least 30 times.

318. Plaintiffs Barragan, Diaz, and Ginsberg seek certification on behalf of a subclass defined as follows ("New York Subclass"):

> **New York Subclass**: All persons in New York who have used a Recalled Device at least 30 times.

319. Plaintiffs King, Bartalo, and Margoles seek certification on behalf of a subclass defined as follows ("North Carolina Subclass"):

> **North Carolina Subclass**: All persons in North Carolina who have used a Recalled Device at least 30 times.

320. Plaintiff Hock seeks certification on behalf of a subclass defined as follows ("Ohio"):

> **Ohio Subclass**: All persons in Ohio who have used a Recalled Device at least 30 times.

321. Plaintiff Wells seeks certification on behalf of a subclass defined as follows ("Oklahoma"):

> **Oklahoma Subclass**: All persons in Oklahoma who have used a Recalled Device at least 30 times.

322. Plaintiffs Hibbard and Hoffman seek certification on behalf of a subclass defined as follows ("Pennsylvania"):

> **Pennsylvania Subclass**: All persons in Pennsylvania who have used a Recalled Device at least 30 times.

323. Plaintiff Bonano seeks certification on behalf of a subclass defined as follows ("Puerto Rico"):

> **Puerto Rico Subclass**: All persons in Puerto Rico who have used a Recalled Device at least 30 times.

324. Plaintiff Lamontagne seeks certification on behalf of a subclass defined as follows ("Rhode Island"):

> **Rhode Island Subclass**: All persons in Rhode Island who have used a Recalled Device at least 30 times.

325. Plaintiffs Flannery and Diaz seeks certification on behalf of a subclass defined as follows ("South Carolina"):

> **South Carolina Subclass**: All persons in South Carolina who have used a Recalled Device at least 30 times.

326. Plaintiffs Bakaitis and Kemp seek certification on behalf of a subclass defined as follows ("Tennessee"):

> **Tennessee Subclass**: All persons in Tennessee who have used a Recalled Device at least 30 times.

327. Plaintiffs Claunch, Panzera, and Malone seek certification on behalf of a subclass defined as follows ("Texas"):

> **Texas Subclass**: All persons in Texas who have used a Recalled Device at least 30 times.

328. Plaintiffs Humphries and Pendleton seek certification on behalf of a subclass defined as follows ("Utah"):

> **Utah Subclass**: All persons in Utah who have used a Recalled Device at least 30 times.

329. Plaintiff Martin seeks certification on behalf of a subclass defined as follows ("Vermont"):

> **Vermont Subclass**: All persons in Vermont who have used a Recalled Device at least 30 times.

330. Plaintiffs Harbor, Heilman, Rose, and Rodgers seek certification on behalf of a subclass defined as follows ("Virginia"):

> **Virginia Subclass**: All persons in Virginia who have used a Recalled Device at least 30 times.

331. Plaintiffs Lopez and Peebles seek certification on behalf of a subclass defined as follows ("Washington"):

> **Washington Subclass**: All persons in Washington who have used a Recalled Device at least 30 times.

332. Plaintiffs Caling, Hamlin, and Rucker seek certification on behalf of a subclass

defined as follows ("West Virginia"):

> **West Virginia Subclass**: All persons in West Virginia who have used a Recalled Device at least 30 times.

333. Together, the Nationwide Class and the Subclasses shall collectively be referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) assigned to this case.

334. As alleged throughout this Complaint, the Philips Defendants and PolyTech Defendants engaged in uniform and standardized conduct towards the Classes. Philips did not differentiate, in its degree of care or candor, its actions or inactions or in the content of its statements or omissions, among individual Class members. The objective facts on these subjects are the same for all Class members. Within each Claim for Relief asserted by the respective Classes, the same legal standards govern. Additionally, many states share the same legal standards and elements of proof, facilitating the certification of multi-state classes for some or all of the claims.

335. No actual conflict of laws exists between the laws of Plaintiffs' home states, and the laws of Class members' states. Or alternatively, any potential conflict is a false one. The lack of conflict, or the false conflict, between the laws of Plaintiffs' home states and the laws of Class members' states means it is appropriate to certify the Class under the laws of the aforementioned states, District of Columbia, and District of Puerto Rico.

336. Plaintiffs reserve the right to adjust, modify, or narrow the Class prior to class certification.

337. The rights of each member of the Class were violated in a similar fashion based upon Philips' uniform actions.

338. This action has been brought and may be properly maintained as a class action for

the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. The proposed Class contains at least millions of individuals who used a Recalled Device. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiffs at this time, but the Class members are readily ascertainable and can be identified by Philips' records and records of third parties, such as durable medical equipment providers.

b. Existence and Predominance of Common Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

i. Whether Philips and/or PolyTech was negligent in manufacturing and selling the Recalled Devices;

ii. Whether Philips and/or PolyTech failed to warn consumers regarding the risks of the Recalled Devices;

iii. Whether Philips' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;

iv. Whether Philips and/or PolyTech is strictly liable for the manufacture and sale of the Recalled Devices;

v. Whether Philips breached the express warranties to Plaintiffs and the Class;

vi. Whether Philips breached its implied warranties to Plaintiffs and the Class;

vii. Whether the chemicals in or emitted from the polyester-based polyurethane

foam in the Recalled Devices are proven hazardous substances;

viii. Whether Plaintiffs and Class members have been significantly exposed to components of the polyester-based polyurethane foam in the Recalled Devices;

ix. Whether Plaintiffs and Class members are at an increased risk of illness, disease, or disease process because of their exposure to components of the polyester-based polyurethane foam in the Recalled Devices;

x. Whether components of the polyester-based polyurethane foam in the Recalled Devices have caused subcellular or other physiological changes in Plaintiffs and Class members;

xi. Whether early detection of illness, disease or disease process will provide benefits to Plaintiffs and Class members;

xii. The appropriate nature of class-wide equitable relief; and

xiii. Whether Philips should be ordered to disgorge, for the benefit of Class members, all or part of their ill-gotten profits received from the sale of defective Recalled Devices and/or to make full restitution to Plaintiffs and Class members.

c. Typicality: Plaintiffs' claims are typical of the claims of all members of the Class. Plaintiffs and Class members all suffered the same type of harm, including exposure to the Foam Toxins, cellular and/or genetic injury, cancer, and/or an increased risk of developing cancer, but have not yet been diagnosed with cancer. Plaintiffs bring claims under the same legal and remedial theories as the class. Plaintiffs' claims arise out of the same set of facts and conduct as the Class members.

d. Adequacy: Plaintiffs are adequate representatives of the Class because their

interests do not conflict with the interests of the Class that they seek to represent; they have retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiffs and their counsel.

e. Rule 23(b)(2): Defendants have acted on grounds that apply generally to Class members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Classes as a whole. Each named Plaintiffs and Class Representative has suffered exposure to Foam Toxins at levels sufficient to necessitate the medical monitoring and other relief sought in this Complaint, and can establish such sufficiency through common proof and evidence.

f. Predominance and Superiority: Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class members, and a class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiffs and the Class. Each named Plaintiff and Class Representative has suffered exposure to Foam Toxins at levels sufficient to necessitate the medical monitoring and other relief sought in this Complaint, and can establish such sufficiency through common proof and evidence. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Philips' and PolyTech's conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for

inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court. Plaintiffs' counsel, highly experienced in product liability litigation, consumer litigation, class actions, and federal court litigation, foresee the efficient management of this case as a class action.

g. Rule 23(c)(4) Issues Class: To the extent the Court determines there are material differences in the relevant laws and that such differences present class manageability issues precluding Independent Claim and/or Remedy class certification for all purposes, Plaintiffs submit that an Independent Claim and a Remedy issue class is appropriate for determination of common material fact issues in the case, and are predicates for the entitlement to medical monitoring (such as exposure, contamination, misconduct, increased risk, existence of testing and benefit of testing, among others).

VII. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

NEGLIGENCE
(Individually and on Behalf of the Class and Subclasses)

339. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein and further allege as follows:

340. Plaintiffs bring this claim on behalf of themselves and all Class members residing in all U.S. jurisdictions.

341. Philips and PolyTech owed a duty to Plaintiffs and Class members to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of the Recalled Devices.

342. Philips and PolyTech owed a duty to Plaintiffs and Class members to ensure that the Recalled Devices it sold in the United States were safe, did not expose patients using the devices to toxic substances, and/or complied with current best manufacturing practices and regulatory requirements.

343. Philips and PolyTech owed a duty of care to Plaintiffs and Class members; because they were the foreseeable, reasonable, and probable users of the Recalled Devices. Philips and PolyTech knew, or should have known, that the Recalled Devices were not safe, exposed their users to toxic and carcinogenic compounds, and/or did not comply with best manufacturing practices and regulatory requirements. Philips and PolyTech were in the best position to uncover and remedy these shortcomings.

344. Philips and PolyTech negligently designed and manufactured the Recalled Devices, causing patients using the Recalled Devices to be exposed to the Foam Toxins, which are carcinogenic and/or toxic.

345. Philips and PolyTech failed to discharge its duties of reasonable care. Philips and PolyTech inadequately conducted or oversaw the design, manufacture, testing, labeling, distribution, marketing, warnings, disclosures, and sale of the Recalled Devices. Philips and PolyTech knew that the aforesaid wrongdoing would damage Plaintiffs and Class members.

346. Philips and PolyTech negligently failed to promptly and immediately warn and disclose to Plaintiffs and Class members, and the medical and regulatory communities, of the potential and actual danger posed by the PE-PUR foam in the Recalled Devices as soon as it was

discovered, delaying notice of this harmful and potentially fatal toxic exposure to carcinogens and thus causing continued exposure to the carcinogenic and/or hazardous compounds, and delaying necessary medical testing, examinations, surveillance, and treatment.

347. Philips' and PolyTech's negligent or grossly negligent conduct created and then exacerbated an unreasonable and dangerous condition for Plaintiffs and Class members.

348. Philips and PolyTech acted with recklessness and willful and wanton disregard for the health of Plaintiffs and Class members.

349. Philips' and PolyTech's unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiffs and Class members and created a foreseeable risk of harm to Plaintiffs and Class members.

350. As a direct and proximate result of Philips' and PolyTech's negligent conduct, Plaintiffs and Class members have suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer and other diseases, necessitating notice to all Class members, sufficient funding for the tests and evaluations of each Class member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

351. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such

further relief as the Court deems equitable and just.

SECOND CLAIM FOR RELIEF

NEGLIGENCE PER SE
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

352. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein and further allege as follows:

353. At all times, Philips had an obligation to comply with applicable statutes and regulations, including relevant and applicable statues and regulations promulgated by the FDA.

354. Philips utilized the 510(k) process to receive clearance for each of its Recalled Devices except the E30 ventilator which was marketed under an EUA.

355. Philips' actions as described herein violated applicable statutes and regulations related to the 510(k) application process, including but not limited to 21 C.F.R. § 807 *et seq.*, and parallel state law requirements.

356. Philips' actions as described herein violated applicable statutes and regulations related to its duty to monitor, investigate, evaluate and timely report issues with foam degradation, including 21 C.F.R. part 803 and 21 C.F.R. § 820.198, and parallel state law requirements.

357. Plaintiffs are within the class of persons that these statutes and regulations are intended to protect.

358. Plaintiffs' injuries and/or symptoms are the type of harm that these statutes and regulations are intended to prevent.

359. Philips' violations of the foregoing statutes and regulations, among others, constitutes negligence per se.

360. As a direct and proximate cause of Philips' negligence, Plaintiffs and Class members have suffered cellular and genetic injury that creates and/or increases the risk that

Plaintiffs will develop cancer and other diseases, necessitating notice to all Class members, sufficient funding for the tests and evaluations of each Class member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

361. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

THIRD CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION AND OMISSION
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

362. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein and further allege as follows:

363. Philips had a duty to tell Plaintiffs and the public the truth about the risks and harms associated with the Recalled Devices.

364. Philips failed to advise Plaintiffs of the material fact that the Recalled Devices posed serious health risks to users. Philips concealed from Plaintiffs information regarding the adverse health effects posed by the Recalled Devices. Philips misrepresented to Plaintiffs that the Recalled Devices were safe for use.

365. Philips was under a duty to disclose to Plaintiffs the serious health risks posed to

users because: (a) Philips was in a superior position to Plaintiffs to know the risks associated with the use of the Recalled Devices; (b) Philips was in a superior bargaining position to Plaintiffs in determining whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, and websites; (c) Philips made representations regarding the safety of the Recalled Devices and had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices, once Philips became aware of such serious health risks; (d) Philips knew that the Plaintiffs could not reasonably have been expected to learn or discover the serious health risks posed by use of the Recalled Devices prior to using the Recalled Devices, given the representations, concealed material information, and omissions by Philips in their packaging, labels, advertising, and websites; and (e) Philips had a duty to disclose information related to the health and safety of its products.

366. Philips breached its duty by falsely representing to Plaintiffs and the public that the Recalled Devices were safe for use when Philips knew or should have known that the Recalled Devices were defective and had not been properly or adequately tested.

367. Philips failed to exercise ordinary care in the representation of the Recalled Devices during its manufacturing, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, in that Philips negligently misrepresented the safety and efficacy of the devices.

368. As a direct and proximate cause of Philips' material omissions, misrepresentations, and concealment of material information regarding the health effects to users of the Recalled Devices, Plaintiffs have suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer and other diseases, necessitating notice to all Class members, sufficient funding for the tests and evaluations of each Class member, and sufficient funding for

necessary ongoing tests, evaluations, and treatment.

369. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FOURTH CLAIM FOR RELIEF

MEDICAL MONITORING
(Individually, on Behalf of the Class, and on behalf of the Colorado, Connecticut, Delaware, District of Columbia, Florida, Massachusetts, Montana, New Hampshire, Pennsylvania, Utah, and West Virginia Subclasses)

370. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein and further allege as follows:

371. Plaintiffs bring an independent claim of medical monitoring against Philips and PolyTech. Plaintiffs bring this claim on behalf of themselves and Class members residing in the following U.S. jurisdictions: Colorado, Connecticut, Delaware, the District of Columbia, Florida, Massachusetts, Montana, New Hampshire, Pennsylvania, Utah, and West Virginia. Should the relevant law change in any U.S. jurisdiction not mentioned above, Plaintiffs reserve the right to amend accordingly.

372. As a proximate result of Philips' and PolyTech's acts and omissions, Plaintiffs and Class members are at an increased risk of developing cancer and other illnesses, diseases, and

disease processes above the normal base-level risk.

373. As alleged above, the Recalled Devices contained defective PE-PUR foam that exposed patients using the devices to the Foam Toxins, which are known to cause cancer in humans.

374. Plaintiffs and Class members may not develop cancer or various adverse health effects for many years.

375. Plaintiffs and Class members are at an increased risk as they, persistently inhaled, consumed, and/or ingested the Foam Toxins for extended periods of time (some as many as several years) and as a result were exposed to critical levels of multiple toxic and carcinogenic compounds.

376. Upon information and belief and based upon the internal and external investigations now made public, the Plaintiffs and Class members are at a substantially increased risk as they were exposed to multiple Foam Toxins.

377. The Foam Toxins are hazardous, life-threatening, toxic substances that are known to cause cancer and other illnesses, diseases, and disease processes in humans.

378. Plaintiffs and Class members are at an increased risk of, *inter alia*, cancer, as they were exposed to, inhaled, consumed, and/or ingested the Foam Toxins in quantities, and over periods of time sufficient to establish levels of exposure that are hazardous to health, and sufficient to cause cancer and other serious ailments, or increase the risk of developing cancer and other serious ailments.

379. The exposure was solely and proximately caused by Philips' and PolyTech's acts and omissions, including: their failure to adequately design and manufacture their Recalled Devices to satisfy applicable standards imposed by law and regulation; their failure to address known issues with the PE-PUR foam during quality control testing; their material

misrepresentations, false statements, and other deceptive practices in continuing to claim that the Recall Devices were safe for use.

380. Philips and PolyTech owed duties to the Plaintiffs and Class members: to ensure and warrant that the Recalled Devices were indeed designed and manufactured to satisfy applicable standards imposed by law and regulation; to disclose to Class members any defect or other potential health hazard known or discoverable by Philips and PolyTech; and to ensure that the Recalled Devices were safe, reliable, and non-hazardous for human consumption—their intended purpose.

381. As alleged above, Philips' and PolyTech's negligent acts and omissions resulted in, among other things, an increased risk of developing cancer or other serious health condition for all Plaintiffs and Class members. Cancer is a serious disease that causes life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, test and/or monitoring procedures exist and are readily available to detect cancer and other deleterious health conditions in patients. These technologies, tools tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. The existing scientific methods include, but are not limited to: blood and laboratory tests; physical examinations; imaging; colonoscopies, endoscopies, and other similar methods for examination; biopsies; pathologic, histologic, and oncologic evaluations; and oncologic, histologic, surgical and other necessary medical consultations.

382. Early detection of cancer and other serious health conditions in patients is one of the best, and sometimes the only, means to treat cancer and other ailments such that they do not cause lasting, permanent injury, illness, or death.

383. Early detection of cancer and other serious health conditions in patients necessarily

allows patients to avail themselves of myriad forms of treatment, each of which is capable to altering the course of the illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate injury.

384. The tests and treatments for the early detection and treatment of cancer and other serious health conditions must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because cancer screenings associated with the Foam Toxins may not be conducted with the frequency necessary to identify cancer in the absence of exposure to the Foam Toxins, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Further, Plaintiffs and Class members require more frequent screenings not within the purview of routine medical exams.

385. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FIFTH CLAIM FOR RELIEF

PRODUCTS LIABILITY-DESIGN DEFECT
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

386. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as is fully set forth herein and further allege as follows:

387. At all times herein mentioned, Philips and PolyTech were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, which are defective and unreasonably dangerous.

388. Plaintiffs were foreseeable users of the Recalled Devices and Philips and PolyTech knew that Plaintiffs would use the Recalled Devices.

389. The Recalled Devices are defective in design because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release particles and off-gas chemicals, including TDA, TDI, DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects.

390. Philips and PolyTech knew or should have known that the defective conditions of the Recalled Devices made the Recalled Devices unreasonably dangerous to Plaintiffs.

391. The Recalled Devices were unreasonably dangerous when used by ordinary users such as Plaintiffs who used the Recalled Devices as they were intended to be used.

392. The Recalled Devices are dangerous to an extent beyond what would be contemplated by the ordinary user of the Recalled Devices.

393. The defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe, and the device was in this defective condition at the time it left the hands of Philips. The Recalled Devices reached Plaintiffs without substantial change in the condition in which they were designed, manufactured, labeled, sold, distributed, marketed,

promoted, supplied, and otherwise released into the stream of commerce.

394. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable diligence, the defective nature of the subject devices. Further, in no way could Plaintiffs have known that Philips and PolyTech had designed, developed, and manufactured the subject devices in a way as to make the risk of harm or injury outweigh any benefits.

395. Safer alternative machines and designs were available which did not have an unreasonable risk of harm as the Recalled Devices and their unsafe PE-PUR foam, for example devices manufactured by other manufacturers.

396. At the time the Recalled Devices left Philips' possession and later were used by Plaintiffs, the Recalled Devices were in a condition that made them unreasonably dangerous to Plaintiffs.

397. The Recalled Devices used by Plaintiffs were expected to and did reach Plaintiffs without substantial change in the condition in which the Recalled Devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

398. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the Recalled Devices were intended to be used.

399. Philips and PolyTech researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed the defective Recalled Devices which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiffs, and Philips is therefore strictly liable for the injuries sustained by Plaintiffs.

400. As a direct and proximate result of each Philips' and PolyTech's conduct, Plaintiffs and Class members have been injured and suffered damages, in that their use of the Recalled

Devices increased their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses.

401. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SIXTH CLAIM FOR RELIEF

NEGLIGENT DESIGN
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

402. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein and further allege as follows:

403. At all times herein mentioned, Philips and PolyTech were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, which are defective and unreasonably dangerous.

404. At all times relevant to this action, Philips and PolyTech had a duty to design, manufacture, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the Recalled Devices with reasonable and due care for the safety and well-being of users, including Plaintiffs who used the Recalled Devices.

405. Plaintiffs were foreseeable users of the Recalled Devices, and Philips and PolyTech

knew that Plaintiffs would use the Recalled Devices.

406. It was foreseeable that the Recalled Devices would be used with the Accessory Humidifiers contributing to humidity; and that they could be used in many climates, and stored in very warm settings, as noted by their own environmental specifications, with said condition contributing to rapid foam degradation.

407. The Recalled Devices are defective in design because the PE-PUR foam comprising part of the devices is subject to degradation and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release the Foam Toxins, which are then inhaled and ingested by patients using the Recalled Devices. The Foam Toxins cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects.

408. The foreseeable risks of using the Recalled Devices, particularly respiratory illnesses up to and including death, significantly outweigh the benefits conferred upon patients using the subject devices.

409. Philips and PolyTech knew or should have known that the defects of the Recalled Devices made the Recalled Devices unreasonably dangerous

410. Philips and PolyTech continued to manufacture and distribute the Recalled Devices after Philips and PolyTech knew or should have known of the Recalled Devices adverse effects or the availability of safer designs.

411. The Recalled Devices were unreasonably dangerous when used by Plaintiffs, who followed the instructions provided by Philips and used the Recalled Devices with common knowledge of their characteristics and according to their common usage.

412. At the time the Recalled Devices left Philips' possession and later were used by Plaintiffs, the Recalled Devices were in a condition that made them unreasonably dangerous to Plaintiffs.

413. The Recalled Devices used by Plaintiffs were expected to and did reach Plaintiffs without substantial change in the condition in which the Recalled Devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

414. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the Recalled Devices were intended to be used.

415. Philips and PolyTech had superior knowledge of the Recalled Devices and owed a duty of care to Plaintiffs.

416. Reasonable alternative designs existed for the subject devices which would have eliminated or reduced the risk of inhalation of carcinogenic materials and VOCs.

417. Philips and PolyTech failed to exercise reasonable and due care under the circumstances and breached their duty of care.

418. As a direct and proximate cause of Philips' and PolyTech's negligence, Plaintiffs and Class members have suffered injury

419. In addition, as a direct and proximate cause of Phillips' and PolyTech's negligence, Plaintiffs and Class members may suffer cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer and other diseases, necessitating notice to all Class members, sufficient funding for the tests and evaluations of each Class member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

420. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation

of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SEVENTH CLAIM FOR RELIEF

STRICT LIABILITY - FAILURE TO WARN
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

421. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein and further allege as follows:

422. Philips and PolyTech designed, manufactured, and sold the Recalled Devices.

423. Plaintiffs were foreseeable users of the Recalled Devices.

424. The Recalled Devices are defective because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release chemicals and particles, including but not limited to TDA, TDI, DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects.

425. Philips and PolyTech knew that the defective condition of the Recalled Devices made the devices unreasonably dangerous to users such as Plaintiffs.

426. The Recalled Devices are dangerous when used by ordinary users who used the devices as intended.

427. The Recalled Devices are dangerous to an extent beyond that contemplated by ordinary users of the devices.

428. Philips and PolyTech knew or should have known of the defects in the Recalled Devices at the time Philips and PolyTech sold or provided the Recalled Devices that were used by Plaintiffs.

429. At the time the Recalled Devices left Philips' possession, the Recalled Devices were defective and in a condition that made them unreasonably dangerous to Plaintiffs.

430. At the time Plaintiffs used the Recalled Devices, the devices were defective and in a condition that made them unreasonably dangerous to Plaintiffs.

431. The Recalled Devices used by Plaintiffs was expected to and did reach Plaintiffs without substantial change in the condition in which the devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

432. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the devices were intended to be used.

433. The Recalled Devices are defective because Philips and PolyTech failed to warn or instruct that the PE-PUR foam in the Recalled Devices can degrade and emit dangerous and carcinogenic Foam Toxins and particles, posing a serious risk to users.

434. Philips and PolyTech further failed to warn or instruct that the Recalled Devices had not been adequately or properly tested.

435. The warning and instructions that accompanied the Recalled Devices failed to provide the level of information that ordinary consumers, including Plaintiffs, would expect when

using the product in a manner reasonably foreseeable to Philips and PolyTech.

436. Philips and PolyTech further failed to warn or instruct that the Recalled Devices, when used in conjunction with the Accessory Humidifiers, would hasten the degradation of the foam and make the Recalled Devices especially dangerous.

437. Philips and PolyTech further failed to warn or instruct that the Recalled Devices should not be stored in warm climates and conditions, and that warm temperatures and humidity would hasten the degradation of the foam, and make the Recalled Devices especially dangerous.

438. Philips and PolyTech further failed to warn or instruct that the Recalled Devices should not be used in conjunction with the SoClean ozone cleaning system which Philips now claims can hasten or cause the degradation of the foam and make the Recalled Devices especially dangerous.

439. Had Plaintiffs received proper or adequate warnings or instructions as to the risks of using the Recalled Devices, Plaintiffs would not have used the Recalled Devices.

440. Had Plaintiffs received proper or adequate warnings or instructions as to the storage, climate and cleaning conditions and protocols, they would have heeded such warnings to mitigate the risk of premature foam degradation.

441. Philips and PolyTech researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed the defective Recalled Devices which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiffs, and Philips and PolyTech are therefore strictly liable for the injuries sustained by Plaintiffs.

442. As a direct and proximate result of Philips' and PolyTech's failure to warn or disclose information, Plaintiffs and Class members have been injured and suffered damages, in

that their use of the Recalled Devices increased their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses.

443. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

EIGHTH CLAIM FOR RELIEF

NEGLIGENT FAILURE TO WARN
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

444. Plaintiffs reallege and incorporate by reference the allegations set forth in the Complaint as is fully set forth herein and further allege as follows:

445. Plaintiffs bring this claim on behalf of themselves and all Class members residing in all U.S. jurisdictions.

446. Even though the Recalled Devices are subject to degradation release of the Foam Toxins—which cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects— Philips and PolyTech failed to warn Plaintiffs and Class members, and the medical and regulatory communities as soon as this risk was suspected or known.

447. Philips' and PolyTech's failure to warn was intentional, reckless, and in wanton and willful disregard for the rights and health of Plaintiffs and Class Members, causing exposure to the Foam Toxins—as well as delay of diagnosis and treatment.

448. To the extent privity may be required, Plaintiffs and Class members can establish privity with Philips and PolyTech or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs and Class members relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

449. Alternatively, Plaintiffs and Class members were foreseeable third-party beneficiaries of Philips's and PolyTech's sale of the Recalled Devices.

450. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the devices were intended to be used.

451. As a direct and proximate result of each Defendant's failure to warn or disclose information, Plaintiffs and Class members have been injured and suffered damages, in that their use of the Recalled Devices increased their risk of developing cancer, cardiac injuries, respiratory issues, kidney injuries, adverse effects to other organs, and other illnesses.

452. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such

further relief as the Court deems equitable and just.

NINTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (Individually, on Behalf of the Class, and on Behalf of the Subclasses)

453. Plaintiffs reallege and incorporate by reference the allegations set forth in the Complaint as though fully set forth herein and further allege as follows:

454. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the provider of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiffs and Class members that the Recalled Devices were of merchantable quality and safe for their ordinary and intended use.

455. Such implied warranty of merchantability, contained in U.C.C. § 2-314, has been codified in each state. See, e.g., Ala. Code §§ 7-2-314, *et seq.*; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq.*; Cal. Com. Code §§ 2314, *et seq.*; Colo. Rev. Stat. §§ 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, §§ 2-314, *et seq.*; D.C. Code Ann. §§ 28:2-314, *et seq.*; Fla. Stat. Ann. §§ 672.314, *et seq.*; O.C.G.A. §§ 11-2-314, *et seq.*; Haw. Rev. Stat. §§ 490:2-314, *et seq.;* Idaho Code §§ 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. §§ 26-1-2-314, *et seq.*; Iowa Code Ann. §§ 554.2314, *et seq.*; Kan. Stat. Ann. §§ 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*; Md. Code Ann., Com. Law §§ 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*; Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*; Minn. Stat. Ann. §§ 336.2-314, *et seq.*; Miss. Code Ann. §§ 75-2-314, *et seq.*; Mo. Rev. Stat. §§ 400.2-314, *et seq.*; Mont. Code Ann. §§ 30-2- 314, *et seq.*; Neb. Rev. Stat. §§ 2-314, *et seq.*; Nev. Rev. Stat. §§ 104.2314, *et seq.*; N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*; N.J. Stat. Ann. §§ 12A:2-314, *et seq.*; N.M. Stat.

Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law §§ 2-314, *et seq.*; N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*; N.D. Cent. Code §§ 41-02-31, *et seq.*; Ohio Rev. Code Ann. §§ 1302.27, *et seq.*; Okla. Stat. tit. 12A, §§ 2-314, *et seq.*; Or. Rev. Stat. §§ 72.3140, *et seq.*; 13 Pa. Stat. Ann. §§ 2314, *et seq.*; R.I. Gen. Laws §§ 6A-2-314, *et seq.*; S.C. Code Ann. §§ 36-2-314, *et seq.*; S.D. Codified Laws §§ 57A-2-314, *et seq.*; Tenn. Code Ann. §§ 47-2-314, *et seq.*; Tex. Bus. & Com. Code §§ 2.314, *et seq.*; Utah Code Ann. §§ 70A-2- 314, *et seq.*; Va. Code Ann. §§ 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, §§ 2-314, *et seq.*; Wash. Rev. Code §§ 62A.2-314, *et seq.*; W. Va. Code §§ 46-2-314, *et seq.*; Wis. Stat. Ann. §§ 402.314, *et seq.*; and Wyo. Stat. Ann. §§ 34.1-2- 314, *et seq*.

456. Philips breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth herein rendering them unsuitable and unsafe for personal use.

457. Had Plaintiffs and Class members known the Recalled Devices were unsafe for use, they would not have used them and jeopardized their health.

458. To the extent privity may be required, Plaintiffs and Class members can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs and Class members relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

459. Alternatively, Plaintiffs and Class members were foreseeable third-party beneficiaries of Philips' sale of the Recalled Devices.

460. Plaintiffs are not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for nearly a year.

461. Moreover, long before the recall, complaints, internal testing, communications with

suppliers, and eventually FDA action put Philips on notice of these issues.

462. As a direct and proximate result of Philips' conduct, Plaintiffs and Class members have been injured and suffered damages, in that their use of the Recalled Devices increased their risk of developing cancer, cardiac injuries, respiratory issues, kidney injuries, adverse effects to other organs, and other illnesses.

463. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

TENTH CLAIM FOR RELIEF

BREACH OF THE IMPLIED WARRANTY OF USABILITY (Individually, on Behalf of the Class, and on Behalf of the Subclasses)

464. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as if fully set forth herein and further allege as follows:

465. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the providers of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiffs that the Recalled Devices were usable for their ordinary and intended use.

466. Such implied warranty arises under U.C.C. § 2-314(3) as adopted in each state.

467. Such implied warranty of usability, contained in U.C.C. § 2-314, has been codified

in each state. *See, e.g.,* Ala. Code §§ 7-2-314, *et seq.*; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq.*; Cal. Com. Code §§ 2314, *et seq.*; Colo. Rev. Stat. §§ 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, §§ 2-314, *et seq.*; D.C. Code Ann. §§ 28:2-314, *et seq.*; Fla. Stat. Ann. §§ 672.314, *et seq.*; O.C.G.A. §§ 11-2-314, *et seq.*; Haw. Rev. Stat. §§ 490:2-314, *et seq.*; Idaho Code §§ 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. §§ 26-1-2-314, *et seq.*; Iowa Code Ann. §§ 554.2314, *et seq.*; Kan. Stat. Ann. §§ 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*; Md. Code Ann., Com. Law §§ 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*; Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*; Minn. Stat. Ann. §§ 336.2-314, *et seq.*; Miss. Code Ann. §§ 75-2-314, *et seq.*; Mo. Rev. Stat. §§ 400.2-314, *et seq.*; Mont. Code Ann. §§ 30-2-314, *et seq.*; Neb. Rev. Stat. §§ 2-314, *et seq.*; Nev. Rev. Stat. §§ 104.2314, *et seq.*; N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*; N.J. Stat. Ann. §§ 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law §§ 2-314, *et seq.*; N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*; N.D. Cent. Code §§ 41-02-31, *et seq.*; Ohio Rev. Code Ann. §§ 1302.27, *et seq.*; Okla. Stat. tit. 12A, §§ 2-314, *et seq.*; Or. Rev. Stat. §§ 72.3140, *et seq.*; 13 Pa. Stat. Ann. §§ 2314, *et seq.*; R.I. Gen. Laws §§ 6A-2-314, *et seq.*; S.C. Code Ann. §§ 36-2-314, et seq.; S.D. Codified Laws §§ 57A-2-314, et seq.; Tenn. Code Ann. §§ 47-2-314, *et seq.*; Tex. Bus. & Com. Code §§ 2.314, *et seq.*; Utah Code Ann. §§ 70A-2-314, *et seq.*; Va. Code Ann. §§ 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, §§ 2-314, *et seq.*; Wash. Rev. Code §§ 62A.2-314, *et seq.*; W. Va. Code §§ 46-2-314, et seq.; Wis. Stat. Ann. §§ 402.314, *et seq.*; and Wyo. Stat. Ann. §§ 34.1-2-314, *et seq.*

468. Through usage of trade, manufacturers of prescription drugs and medical devices impliedly warrant that their products are usable for the end consumer.

469. Philips breached the implied warranty of usability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained defects as set forth herein rendering them unusable.

470. Philips, its agents and employees knew or should have known that the Recalled Devices suffer from a defect that causes negative health effects and/or places persons at risk for negative health effects to such an extent that the products are unusable.

471. Philips' Recall announcement instructed Plaintiffs to not use Recalled Devices because of the health risks. This confirmed the true nature of the products, which at all times were adulterated and worthless.

472. To the extent privity may be required, Plaintiffs can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

473. Alternatively, Plaintiffs were foreseeable third-party beneficiaries of Philips' sale of the Recalled Devices.

474. Had Plaintiffs known that Philips had breached the implied warranty of usability for their Recalled Devices, they would not have used the Recalled Devices.

475. As a direct and proximate result of Philips' conduct, Plaintiffs and Class members have been injured and suffered damages, in that their use of the Recalled Devices increased their risk of developing cancer, cardiac injuries, respiratory issues, kidney injuries, adverse effects to other organs, and other illnesses.

476. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation

of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

ELEVENTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTIES
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

477. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein and further allege as follows:

478. Philips warranted that all of the Recalled Devices "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."[203]

479. Philips breached this express warranty in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth here, rendering them unsuitable and unsafe for personal use.

480. Further, through Philips' public statements, descriptions, and promises relating to the Recalled Devices, Philips expressly warranted that the products were safe and effective for their intended use.

481. Had Plaintiffs known the Recalled Devices were unsafe for use, they would not

[203] *See, e.g.,* Warranty Exemplars: Dreamstation (Exhibit "B-1" hereto), at 29; REMstar SE (Exhibit "B-2" hereto), at 21; Trilogy 100 (Exhibit "B-3" hereto), at 163.

have used them.

482. Philips has breached its warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs reasonably expected, at the time of use, that the Recalled Devices were safe for their ordinary and intended use.

483. To the extent privity may be required, Plaintiffs can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

484. Alternatively, Plaintiffs were foreseeable third-party beneficiaries of Philips sale of the Recalled Devices.

485. Plaintiffs are not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for nearly a year.

486. As a direct and proximate result of each Defendant's conduct, Plaintiffs and Class Members have been injured and suffered damages, in that their use of the Recalled Devices increased their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses.

487. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure

to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

TWELFTH CLAIM FOR RELIEF

FRAUD/FRAUDULENT CONCEALMENT
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

488. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as if fully set forth herein and further allege as follows:

489. Philips knew that the Recalled Devices posed serious health risks to users.

490. Philips failed to advise Plaintiffs of the material fact that the Recalled Devices posed serious health risks to users. Philips concealed from Plaintiffs information regarding the adverse health effects posed by the Recalled Devices. Philips misrepresented to Plaintiffs that the Recalled Devices were safe for use.

491. Philips were under a duty to disclose to Plaintiffs the serious health risks posed to users because: (a) Philips was in a superior position to Plaintiffs to know the risks associated with the use of the Recalled Devices; (b) Philips was in a superior bargaining position to Plaintiffs in determining whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, and websites; (c) Philips made representations regarding the safety of the Recalled Devices and had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices, once Philips became aware of such serious health risks; (d) Philips knew that the Plaintiffs could not reasonably have been expected to learn or discover the serious health risks posed by use of the Recalled Devices prior to using the Recalled Devices, given the representations, concealed material information, and omissions by Philips in its packaging, labels, advertising, and websites; and (e) Philips had a duty to disclose information related to the health and safety of its products.

492. Philips intentionally, knowingly, and recklessly allowed its packaging, labels, advertisements, promotional materials, and websites to mislead Plaintiffs to believe that the Recalled Devices were safe for use.

493. Philips knew that its omissions, concealment, and representations in its packaging, labels, advertisements, promotional materials, and websites regarding the Recalled Devices were false, deceptive, inadequate, and misleading, and that the Recalled Devices contained PE-PUR foam and thus could cause adverse health effects to users of the Recalled Devices.

494. Philips concealed from Plaintiffs and misrepresented material information regarding the serious health risks posed to users of the Recalled Devices, by failing to include material information in its packaging, labels, advertisements, promotional materials, and websites.

495. The information undisclosed and concealed by Philips to Plaintiffs was material, as a reasonable consumer would find information regarding serious adverse health risks associated with the use of the Recalled Devices important when deciding whether to use the Recalled Devices.

496. As a result of such deceptive packaging, labels, advertisements, promotional materials, and websites, Plaintiffs justifiably and reasonably believed the Recalled Devices were safe for use.

497. Philips intentionally, knowingly, and recklessly made these material omissions and misrepresentations, and concealed material information regarding the adverse health risks associated with the Recalled Devices in its packaging, labels, advertisements, promotional materials, and websites regarding the Recalled Devices to induce Plaintiffs to use the Recalled Devices.

498. Plaintiffs and Class Members relied on Philips' deceptive packaging, labels, advertisements, promotional materials, and websites and purchased and used the Recalled Devices

to their detriment. Given the deceptive manner in which Philips advertised, represented, and promoted the Recalled Devices, such reliance by Plaintiffs and Class Members was reasonable and justified.

499. As a direct and proximate result of Philips' material omissions, misrepresentations, and concealment of material information regarding the adverse health effects to users of the Recalled Devices, Plaintiffs and Class members have been injured and suffered damages, in that their use of the Recalled Devices increased their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses.

500. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

THIRTEENTH CLAIM FOR RELIEF

STATE-LAW PRODUCT LIABILITY ACT CLAIMS
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

501. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as is fully set forth herein and further allege as follows:

502. The Recalled Devices were defectively designed and manufactured, as the Recalled Devices used PE-PUR foam that exposed users to the Foam Toxins.

503. Breathing devices that cause users to inhale and ingest carcinogens, VOCs, and other hazardous materials are, by definition and as detailed above, defectively manufactured.

504. Philips' conduct in defectively manufacturing the Recalled Devices was reckless and taken with wanton and willful disregard for the health of Plaintiffs and Class members.

505. Defendants are strictly liable for the harm caused by or contributed to by the defectively manufactured Recalled Devices.

506. Plaintiffs note that to the extent any claims are deemed not to be subsumed, whether in prior or future orders by the Court, stipulations, or other court filings, Plaintiffs assert all available common law and statutory causes of action available to them under the laws of the states and territories upon which their claims rest.

507. **Connecticut Product Liability Act, Conn Gen. Stat. §§ 52-572m**. Connecticut Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

508. Connecticut Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Connecticut Product Liability Act, Conn Gen. Stat. §§ 52-572m under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, punitive damages, and consumer protection claims.

509. The claims above are brought against all Philips Defendants.

510. **Indiana Product Liability Act, Ind. Code §§ 34-20-1-1**. Indiana Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

511. Indiana Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Indiana Product Liability Act, Ind. Code §§ 34-20-1-1 under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages.

512. The Indiana PLA does not subsume express or implied warranty claims asserted in this Complaint, and therefore Plaintiffs assert those claims under the common law and/or other applicable law causes of action enumerated herein.

513. The claims above are brought against the Philips Defendants named in each common law cause of action preceding and following this Count.

514. **Kansas Product Liability Act, Kansas Stat. Ann. 60:3301, *et seq***. Kansas Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as thought fully set forth herein and further allege as follows.

515. Kansas Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Kansas Product Liability Act, Kansas Stat. Ann. 60-3301 et seq. under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages.

516. The claims above are brought against all Philips Defendants.

517. **New Jersey Product Liability Act, N.J.S.A. 2A:59C-2**. New Jersey Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows:

518. New Jersey Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the New Jersey Product Liability Act, N.J.S.A. 2A:59C-2 under the theories of strict liability - manufacturing defect, strict liability - failure to warn, strict liability - design defect, negligence, negligence per se, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, punitive damages, and consumer protection claims.

519. The New Jersey PLA does not subsume express warranty claims asserted in this Complaint, and therefore Plaintiffs assert that claim under the common law and/or other applicable law causes of action enumerated herein.

520. The claims above are brought against the Philips Defendants named in each common law cause of action preceding and following this Count.

521. **Ohio Product Liability Act, Ohio Rev. Code § 2307.72(A) & (B)**. Ohio Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

522. Ohio Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Ohio Product Liability Act, Ohio Rev. Code § 2307.72(A) & (B) under the theories of strict liability - manufacturing defect, strict liability - failure to warn, strict liability - design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, punitive damages, and consumer protection claims.

523. The Ohio PLA does not subsume claims alleging or sounding in fraud asserted in this Complaint, and therefore Plaintiffs assert those claims under the common law and/or other applicable law causes of action enumerated herein.

524. The claims above are brought against the Philips Defendants named in each

common law cause of action preceding and following this Count.

525. **Tennessee Product Liability Act, Tenn. Code Ann. § 29-28-101 *et seq*.** Tennessee Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

526. Tennessee Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Tennessee Product Liability Act, Tenn. Code Ann. § 29-28-101 et seq. under the theories of strict liability - manufacturing defect, strict liability - failure to warn, strict liability - design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages.

527. The claims above are brought against all Philips Defendants.

528. **Washington Product Liability Act, Wash. Rev. Code Ann. § 7.72.010 *et seq*.** Washington Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

529. Washington Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Washington Product Liability Act, Wash. Rev. Code Ann. § 7.72.010 et seq. under the theories of strict liability - manufacturing defect, strict liability - failure to warn, strict liability - design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages.

530. The Washington PLA does not subsume claims alleging or sounding in fraud asserted in this Complaint, and therefore Plaintiffs assert those claims under the common law and/or other applicable law causes of action enumerated herein.

531. The claims above are brought against the Philips Defendants named in each common law cause of action preceding and following this Count.

532. As a direct and proximate result of Philips' conduct, Plaintiffs and Class members have been injured and suffered damages, in that the Recalled Devices exposed them to the Foam Toxins and thus created and/or increased the risk that Plaintiffs and Class members will develop cancer, respiratory disease, cardiovascular disease, and other abovementioned illnesses.

533. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of the following: (1) notifying and alerting all people exposed to the Foam Toxins as aforesaid of their exposure and the potential consequences, (2) providing for necessary testing, evaluations and screening, and other necessary medical consultations, (3) providing for all necessary medical and surgical procedures for diagnosis and treatment, (4) establishing a panel of scientists to study the effects on the human body of exposure to the Foam Toxins, and (5) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FOURTEENTH CLAIM FOR RELIEF
(Declaratory Judgment under the Declaratory Judgment Act)

534. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as is fully set forth herein and further allege as follows:

535. An actual, substantial, and justiciable controversy has arisen and exists between Plaintiffs and Class members and Philips herein and their respective rights, obligations, and duties with respect to the presence, accumulation, toxic invasion, and/or persistence of the Foam Toxins in the bodies of Plaintiffs and Class members, as a result of Philips' acts and/or omissions.

536. By reason of the foregoing, Plaintiffs and Class members seek a declaratory

judgment against Philips that Philips is liable and responsible for the introduction of the Foam Toxins into Plaintiffs' and Class members' bodies and all equitable and/or injunctive relief, and such other relief as the Court may Order, that the Court deems reasonable and appropriate in relation thereto.

VIII. RELIEF SOUGHT BY THE CLASS

537. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as is fully set forth herein and further allege as follows:

538. Plaintiffs and the proposed Class have sustained and will continue to sustain physical injury and/or irreparable harm in the form of the presence, accumulation, toxic invasion, and/or persistence of the Foam Toxins in their bodies, as a result of Philips' acts and/or omissions.

539. As a result, Plaintiffs and the Class seek equitable and/or injunctive relief for each of the causes of action alleged herein; neither Plaintiffs nor the Class are seeking any compensatory damages for personal injuries through any class-wide claims asserted herein.

540. In particular, Plaintiffs and the Class seek the establishment of an independent panel of scientists, including but not limited to epidemiologists, toxicologists, medical doctors, and/or exposure-risk assessors, to be jointly selected by the parties (the "Foam Toxin Science Panel") and tasked with independently studying, evaluating, reviewing, identifying, publishing, and notifying/informing the Class of the causal connection between any single or combination of Foam Toxins in the human body and any injury, human disease, adverse human health impact, and/or a risk sufficient to warrant any personal injury compensation or future diagnostic medical testing, including medical monitoring that shall be deemed definitive and binding on all the parties, which work, including but not limited to any testing, sampling, or monitoring deemed appropriate by the Foam Toxin Science Panel shall all be funded by Philips.

IX. RELIEF NOT REQUESTED AND RESERVATION OF RIGHTS

541. None of the causes of action asserted herein seeks damages or other relief for economic losses or personal injuries allegedly attributable to Plaintiffs' and Class members' use of a Recalled Device. Such claims will be governed by the Consolidated Second Amended Class Action Complaint for Economic Losses, filed July 6, 2022, and/or the Master Personal Injury Complaint, to be filed by August 22, 2022, pursuant to Pretrial Order #14 (ECF 573), and any additional Short Form Complaints that may be filed (or as otherwise agreed by the parties). The named Plaintiffs in this Complaint expressly reserve their right to seek damages or other relief for economic losses and/or personal injuries they may have suffered, regardless of whether those damages are sought through causes of action alleged herein or otherwise.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

a. Certifying this Action as a class action;

b. Appointing Plaintiff(s) as Class Representative(s), and appointing undersigned counsel as Class Counsel to represent the Class and each Subclass;

c. A finding that Philips and PolyTech are liable pursuant to the above-enumerated causes of action;

d. Awarding appropriate preliminary and/or final injunctive relief;

e. Directing Philips and PolyTech to fund medical monitoring in an amount sufficient to fund necessary notice and medical care, including but not limited to examinations, tests, pathology, blood tests, evaluations, and treatment, as necessary and appropriate;

f. An award of the costs of clinical evaluations, diagnostic testing, and

consultations for the early detection of illness, disease, and disease processes; and the purchase and replacement costs of Recalled Devices in an amount to be determined at trial; or in the alternative, equitable relief in the form of a court-supervised fund for the costs of medical monitoring;

g. Equitable relief and/or an injunction ordering Defendants to provide for and fund the Foam Toxin Science Panel Work described herein;

h. Payment to Plaintiffs and Class members of compensatory damages necessary for their monitoring and care;

i. An award of attorneys' fees and costs;

j. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest; and

k. Such other and further relief as this Court may deem equitable and just.

XI. JURY DEMAND

Plaintiffs and the Class and Subclasses demand a trial by jury on all issues so triable.

Dated: August 22, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was filed via the Court's CM/ECF system on this 22nd day of August 2022 and is available for download by all counsel of record.

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